

# **EXHIBIT III.1**

**UNITED STATES DISTRICT COURT**  
**NORTHERN DISTRICT OF OHIO**  
**EASTERN DIVISION**

IN RE NATIONAL PRESCRIPTION

OPIATE LITIGATION

*This document relates to:*

*The County of Summit, Ohio, et al. v. Purdue Pharma*  
*L.P., et al., Case No. 18-OP-45090*

MDL 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

Report of David S. Egilman MD, MPH

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## 2 BACKGROUND AND QUALIFICATIONS

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My name is Dr. David Egilman. I am a medical doctor and Clinical Professor of Family Medicine at Brown University. I am board certified in Internal Medicine and Preventive-Occupational Medicine. My *curriculum vitae* [Egilman CV hereto attached as **Exhibit A.1**] sets forth more fully my qualifications.

I received a Bachelor of Science degree in Molecular Biology and a degree in Medicine at Brown University. [Egilman CV at 1] I then completed my three year residency in internal medicine at the University of Rochester. [Egilman CV at 1] I helped start a program focused on women's health. I completed NIH's three-year Epidemiology Training Program. [Egilman CV at 1-2] The first year of this program involved training at the Harvard School of Public Health (HSPH), where I was awarded a Master's Degree in Public Health. [Egilman CV at 1-2] At Harvard, I studied industrial hygiene and toxicology; epidemiology; statistics; occupational medicine and law; public policy with respect to occupational and environmental hazards; areas that relate to the specialty of preventive medicine, including education, product design changes and substitution; warnings and risk communication, including regulatory approaches to control; the tort system; environmental law; Food and Drug Administration (FDA) and OSHA law; and the Consumer Product Safety Commission (CPSC). One course that I completed during the program covering various legal and regulatory approaches to control of health hazards was a joint course offered by the Harvard Law School, the Harvard School of Public Health, and the MIT Business School. I spent the second two years of the National Institutes of Health (NIH) Epidemiology Training Program at NIOSH. As part of my assignment I received the training in epidemiology and surveillance provided by the Centers for Disease Control to Epidemic Intelligence Service officers. At NIOSH, I received training in the law as it applied to NIOSH and OSHA medical officers. I was responsible for implementing parts of the OSHA Act relevant to investigation of worker health. I received training in risk communication and warnings at NIOSH. At NIOSH, I received training in industrial hygiene techniques, conduct of epidemiologic studies, and risk analysis -- particularly as it applied to carcinogens and dose assessment. I designed implemented small and large epidemiological studies. I participated in industrial hygiene sampling and became familiar with industrial hygiene monitoring for asbestos and other toxic exposures. While at NIOSH, I completed the NIOSH residency in occupational medicine in 1984. [Egilman CV at 1] At NIOSH I was a uniformed officer of the U.S. Public Health Service. While at NIOSH, my responsibilities included education of workers, employers and members of the public regarding health hazards. I provided this information through a variety of vehicles, including written reports, conferences, mass meetings and face-to-face conversations. NIOSH and the CDC provided training on the mechanisms of effective communication. I completed a third residency in preventive medicine in 1993. [Egilman CV at 1]

Occupational Medicine is the branch of medicine that deals with the prevention and treatment of diseases and injuries that occur as a result of exposure to chemical substances. This specialty deals with the toxicological effects of exposures to chemical substances on the body. The fundamental aspect of this specialty is the determination of which exposures cause disease, and how they do so. My educational and professional background, training

at HSPH and NIOSH, and teaching and publications provide the basis of my expertise in warnings.

I have extensively studied the role of warnings in preventing illnesses and the current and historical techniques for providing warnings. I have published two chapters in the major textbook relating to warning and risk communication. [Egilman CV at 13: Chapter Two "A Brief History of Warnings," and "Consider The Source: Warnings And Anti-Warnings In The Tobacco, Automobile, Beryllium, And Pharmaceutical Industries" in Wogalter Ed., Warnings and Risk Communication]

My first chapter in the book on Warnings and Risk Communication, (the first full chapter in the book) dealt with the history of warnings; the second addressed the adverse effects of marketing on public health, focusing particularly on false reassurance given by product manufacturers to consumers. Both chapters dealt with issues that related to FDA regulatory authority. Some of my publications have dealt with FDA regulations and I cover FDA-related issues in my course. [Egilman CV at 2, 13, & 19]

I also ran a clinic for 12-13 years, treating patients and consulting in occupational medicine for large and small companies. I treated patients with pain from cancer and chronic non-malignant pain and at times prescribed opioids in my practice. [Egilman IMS Data hereto attached as **Exhibit A.2**]

I am licensed to practice medicine in Massachusetts, Rhode Island, and Mississippi. I have published over 100 papers, including 50 original publications in peer-reviewed journals and 78 presentations. I have authored peer-reviewed publications on epidemiology and causation; regulatory science; warnings, anti-warnings, and risk communication; the development of the corporate, medical and scientific communities' knowledge of the health hazards; and corporate influence on science and regulation.

The Asbestos Disease Awareness Organization (ADAO) awarded me the Irving Selikoff Lifetime Achievement Award for my academic contributions to the prevention of asbestos disease. [Egilman CV at 3]

I have taught several courses at Brown University, including the Development of Medical and Scientific Knowledge in the 20th Century; and Science and Power: A Bioethical Inquiry, and currently teach a course in the Brown School of Public Health called, "Science and Power – The Corruption of Public Health." This course deals specifically with the issues outlined in this report: the history of the development of knowledge regarding the health hazards; FDA regulations; warnings and risk communication, including corporate knowledge of health effects of products; the history of the development of government regulations on occupational, consumer and environmental safety; and the history of the development of contemporaneous appropriate public health responses to information regarding the adverse health effects of products on users, including education of product users and product redesign (state of the art). In my course, I compare the medical and scientific information available to the companies with that available to the medical and scientific community.

I have also published on these topics. I have also taught a two-year course for medical students that covered medical ethics, community approaches to public health, and health education.

I served, for over 10 years, as a preceptor to residents in Family Medicine and medical students, supervising the care of patients. I served for 9 years as the Editor in Chief of a major journal: The International Journal of Occupational & Environmental Health. [Egilman CV at 2]

On two occasions I testified before congressional sub-committees on the issues relating to informed consent and corporate responsibility to inform members of the public about health hazards. My testimony concerned the history of informed consent, warnings, and research ethics. In addition, I have published two papers on the topic of the history of the development of informed consent. I was a board member of Citizens for Responsible Care in Research from 1997- 2009. I am currently a board member of The Alliance for Human Research Protection (AHRP). These non-governmental organizations (NGO) deal with the ethical conduct of research.

I have reviewed the history of warnings from the published literature, and from internal corporate documents and organizational documents. I presented several papers on warnings. I teach about warnings at Brown University, including FDA drug-related warnings. I testified before Congress on the history and development of informed consent, as well as on current informed consent practices. I have been accepted as an expert by the court in Keenan v. Parke-Davis et al. PC 84-1667 (Rhode Island) on the issue of warnings and FDA policy. I have also been accepted as a witness on issues that relate to FDA warning policy in the case of Vassallo v. Baxter Healthcare Corporation, 428 Mass. 1 (1998). My affidavit on medical epistemology was cited by the court. I have reviewed corporate documents specifically addressing warning practices throughout this century. I have studied the efficacy of warnings.

Along with my colleague, Susanna Bohme, I co-authored two chapters in a textbook on the history of warnings: Egilman D.S., Bohme S.R. "A Brief History of Warnings" and "Consider the Source: Warnings and Anti-Warnings in the Tobacco Beryllium, Automobile and Pharmaceutical Industries," Handbook of Warnings, ed. Michael Wogalter Mahwah, NJ: Lawrence Erlbaum Associates, 2006. In November of 2004, I presented a lecture at the American Public Health Association Conference entitled, "Occupational Warnings: Protecting People or Protecting Profit?" In addition, in July of 2004 at the Center for Science in the Public Interest (CSPI) conference, I presented a lecture on "The Suppression of Science: How Corporate Interests Hide the Truth." In this talk, I spoke of the need to adequately warn doctors and the public about the health risks of exposure to products, about FDA regulations, and about corporate codes of conduct and ethical standards.

I have presented at the annual American Public Health Association conference off-label marketing and hiding addiction risks. (Egilman DS and Falender J. OxyContin: How Profits Took Priority over Public Health. APHA, Nov 2004.) In February 2013, I presented to the FDA about OxyContin's 12-hour dosing regimen as a contributing cause of opioid addiction. [FDA Presentation Slides and Transcript hereto attached as **Exhibit A.3 and**

**Exhibit A.4]** I have authored a number of articles and presentations pertaining to medical and business warnings issues. (See attached CV for complete list of publications and presentations.)

- Writings and presentations explicitly dealing with warnings and disclosure in business and scientific research and publishing:
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- Bohme SR and Egilman DS. Occupational Warnings: Protecting People or Protecting Profit. APHA, Nov 2004.
- Egilman DS. Panel Member: From Practice to Science: How Application Guides Warning Research. International Ergonomics Association Conference, Jul 2006.
- Other writings and presentations, considering issues relevant to the fields of medical and business practices, including industry influence on research, attorney misconduct in procuring clients, and marketing of products that injure workers and/or consumers:
  - Egilman, D.S., Fehnel, C., Bohme, S.R. Exposing the “Myth” of ABC: A Critique of the Canadian Asbestos Mining Industry-McGill Chrysotile Studies. *Amer J Ind Med* 44:5, 2003.
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- Egilman DS and Bohme SR, Guest Editors. Over a Barrel: Corporate Corruption of Science and Its Effects on Workers and the Environment. *Int J Occup Environ Health* 11(4):331-337, Oct-Dec 2005.
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- Fassler E, Steffen J, Egilman D. Corporate Manipulation of Law and its Impact on Chronic Disease. APHA 2018 Annual Meeting & Expo, San Diego, CA. Nov 10-14, 2018.

I have reached the conclusions stated below to a reasonable degree of medical probability based on my review of the medical and scientific literature, corporate documents, depositions and on my years of training and clinical experience.

### 3 METHODOLOGY

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#### 3.1 STATE OF THE ART MATERIALS REVIEWED

In the course of doing research, publishing peer-reviewed papers, corporate consulting in occupational and environmental health, and teaching courses, I base my opinions on the following sources of information:

- Review of medical literature:
  - Medical journal articles
  - Medical meetings
  - Medical textbooks
  - In order to review medical literature, I conducted computer searches of several different databases including:
    - Index Medicus
    - PubMed
    - NIOSHtic
    - EPA
    - Cancer Lit
    - MedLine
  - In addition, my staff or I reviewed each issue of Index Medicus from 1910 through 1966. (Index Medicus was computerized from 1964 forward and was reviewed by computer following this.)
- Review of published books
- Review of corporate documents
  - I have had access to the entire repository of documents and metadata has had been produced in this litigation. This repository includes production from the following sources:
    - ABCD – Amerisource Bergen
    - Allergan
    - Anda
    - Cardinal Health
    - CVS
    - DDM – Discount Drug Mart
    - Endo
    - HD Smith
    - Henry Schein
    - Insys
    - Janssen
    - Mallinckrodt
    - McKesson
    - Purdue
    - Rite Aid
    - Teva
    - Walgreens

- Walmart
- In addition to these, I reviewed legal complaints filed against opioid manufacturers and distributors in Massachusetts and Florida. When publicly available, I also reviewed the documents cited in these complaints.
- I reviewed the Master Amended Complaint in this litigation.
- My review of corporate documents included but was not limited to the following types of records:
  - Company meetings and correspondence
  - Internal company medical studies
  - Warnings labels and warnings policies
  - Promotional materials
  - Call notes
  - Marketing plans
  - CMEs
- Review of other produced documents
  - I reviewed documents from the Front Groups (organizations used by manufacturers to further promote their objectives)
  - I reviewed produced documents from Key Opinion Leaders
  - I reviewed produced documents from Advocacy Groups
  - I reviewed produced documents from Trade Groups
  - I reviewed produced documents from Professional Societies
- Review of depositions
  - Depositions (including exhibits) reviewed: I reviewed depositions taken in this case (Opiate MDL).

It is my expectation that I will review the Expert Reports of Plaintiffs' and Defendants' Experts once they are made available.

## 3.2 STATE OF THE ART METHODS

I employed systematic search techniques in combination with a grounded theory approach. Grounded theory is an inductive method which allows analytical categories to emerge from the data presented.<sup>1</sup> A method of grounded theory analysis must build and change responsively throughout the research process. The grounded theory approach recognizes that data collection and analysis are inherently interrelated processes and calls for analysis to begin at the time of first data collection. The researcher, therefore, must continually ground their concepts and analyses in the reality of the data, which can protect against researcher bias. As described by Corbin and Strauss, "...the hypotheses are constantly revised during the course of the research until they hold true for the phenomena under study, as evidence in repeated interviews, observations, or documents."<sup>2</sup> This approach has

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<sup>1</sup> Pope, Ziebland, and Mays 2000

<sup>2</sup> Corbin, J. and A. Strauss (1990). "Grounded Theory Research: Procedures, Canons and Evaluative Criteria." *Zeitschrift fur Soziologie* 19(6): 418-427.

been used in analyses of corporate documents, which require the synthesis of a wide variety of information.<sup>3</sup> I have published a number of peer reviewed papers based on this method:

- Steffen JE, Fassler EA, Reardon KJ, Egilman DS. Grave fraudulence in medical device research: a narrative review of the PIN seeding study for the Pinnacle hip system. *Accountability in Research* 25(1):37-66, Jan 2018. DOI: 10.1080/08989621.2017.1405259
- Ross JS, Hill KP, Egilman DS. Guest authorship and ghostwriting in publications related to Rofecoxib: a case study of industry documents from rofecoxib litigation. *JAMA* 299(15):1800-1812, 2008. DOI: 10.1001/jama.299.15.1800
- Hill KP, Ross JS, Egilman DS, Krumholz HM. The ADVANTAGE seeding trial: a review of internal documents. *Ann of Intern Med* 149(4):251-258, 2008.
- Krumholz SD, Egilman DS, Ross JS. Study of Neurontin: titrate to effect, profile of safety (STEPS) trial. *Arch Intern Med* 171(12): 1100-1107.

I initially searched the sources above for key terms identified by me, including:

- Opioids
- Opioid addiction
- Pain
- NSAIDs
- Pseudo-addiction
- Pain treatment
- Analgesic
- Opioid efficacy
- Acupuncture
- Meditation
- Marijuana pain
- Homeopathy

After the emergent subset of documents was reviewed, key themes and concerns were identified, including documents specifically pertaining to evidence-based medicine, third party interest groups, public-private partnerships, EERW study design, chronic pain treatment, return-on-investment for marketing techniques, hospital licensing and accreditation, state medical board licensing, off-label promotion, diversion, and 12-hour dosing regimens. Additional searches were conducted to explore these and other more specific topic areas as they arose. This iterative analysis formed the basis for my state on the art opinions in this case.

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<sup>3</sup> Steinman et al. 2006

### 3.3 EVIDENCE-BASED MEDICINE (EBM) METHODS

Evidence-based medicine (EBM) is an approach to medical decision-making meant to integrate “individual clinical expertise with the best available external clinical evidence from systematic research.”<sup>4,5</sup> David Sackett described the importance of both external clinical evidence and individual clinical experience in providing effective medical care:<sup>6</sup>

*Good doctors use both individual clinical expertise and the best available external evidence, and neither alone is enough. Without clinical expertise, practice risks becoming tyrannized by external evidence, for even excellent external evidence may be inapplicable to or inappropriate for an individual patient. Without current best external evidence, practice risks becoming rapidly out of date, to the detriment of patients.*

The practice of EBM can be outlined in five basic steps:<sup>7,8</sup>

1. Translation of uncertainty to an answerable question
2. Systematic retrieval of best evidence available
3. Critical appraisal of evidence for validity, clinical relevance, and applicability
4. Application of results in practice
5. Evaluation of performance

I implemented EBM in my medical practice beginning in the mid- to late-1980s following the publication of Dr. David Sackett’s landmark book *Clinical Epidemiology*.<sup>9</sup> I also taught EBM to medical students as a Clinical Professor of Family Medicine at Brown University. Since its founding in 2002, I have headed GHETS (Global Health through Education, Training, and Service) and, through the organization, have implemented EBM curriculum in Asia, Africa, and Latin America.

#### 3.3.1 Step 1: Translation of uncertainty to an answerable question

Answerable questions generally fall into two categories: “background” questions designed to examine the problem or disorder itself and “foreground” questions intended to address a specific problem, patient, or situation.<sup>10</sup> Background questions generally comprise of 1) a question root and verb and 2) some aspect of the disorder. Foreground questions usually

<sup>4</sup> Sackett DL. Evidence-based medicine. *Semin Perinatol [Internet]*. 1997 Feb 1 [cited 2019 Feb 28];21(1):3–5. Available from: <https://www.sciencedirect.com/science/article/pii/S0146000597800134>

<sup>5</sup> Sackett DL, Rosenberg WM, Gray JA, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. *BMJ*. 1996;312(7023):71-2.

<sup>6</sup> Sackett DL. Evidence-based medicine. *Semin Perinatol [Internet]*. 1997 Feb 1 [cited 2019 Feb 28];21(1):3–5. Available from: <https://www.sciencedirect.com/science/article/pii/S0146000597800134>

<sup>7</sup> Ibid.

<sup>8</sup> Dawes M, Summerskill W, Glasziou P, et al. Sicily statement on evidence-based practice. *BMC Med Educ*. 2005;5(1):1. Published 2005 Jan 5. doi:10.1186/1472-6920-5-1

<sup>9</sup> Sackett DL, Haynes RB, Tugwell P. *Clinical epidemiology: a basic science for clinical medicine*. 1st ed. Boston, MA: Little, Brown; 1985.

<sup>10</sup> Sackett DL, Straus SE, Richardson WS, Rosenberg W, Haynes RB. *Evidence-Based Medicine: How to Practice and Teach EBM*. 2nd Edition. Edinburgh, UK: Churchill Livingstone; 2000.

contain 1) the patient or problem of interest, 2) the main intervention, 3) comparison interventions, and 4) the desired clinical outcome.

I asked the following background questions:

- What are the treatment options for chronic non-cancer pain?

I asked the following foreground questions:

- In patients with chronic non-cancer pain, how do opioids and NSAIDs compare in terms of efficacy and adverse effects?

### **3.3.2 Step 2: Systematic retrieval of best evidence available**

Once an answerable question has been posed, the researcher must select an evidence resource, execute a search strategy, and then evaluate the evidence summary.<sup>11</sup>

EBM tends to devalue textbooks as a source of best evidence because the information contained within them can quickly become out of date. For a textbook to be a dependable source of evidence, it should be revised frequently, be heavily referenced, and be comprised of evidence selected according to explicit principles of evidence.<sup>12</sup> Evidence databases, such as MEDLINE/PubMed, offer a better means for retrieving the best, most current evidence.

<sup>13</sup>

In order to review medical evidence, I conducted computer searches of several different databases including:

- Index Medicus
- PubMed (MEDLINE)
- NIOSHtic
- EPA
- Cancer Lit
- MedLine

In addition to published evidence, I also searched corporate records for unpublished studies. I have had access to the entire repository of documents produced in this litigation. This repository includes production from the following sources:

- ABCD – Amerisource Bergen
- Allergan
- Anda
- Cardinal Health
- CVS
- DDM – Discount Drug Mart
- Endo
- HD Smith

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<sup>11</sup> Ibid.

<sup>12</sup> Ibid.

<sup>13</sup> Ibid.



- Henry Schein
- Insys
- Janssen
- Mallinckrodt
- McKesson
- Purdue
- Rite Aid
- Teva
- Walgreens
- Walmart

I initially searched the sources above for key terms identified by me, including:

- Opioids
- Opioid addiction
- Pain
- NSAIDs
- Pseudo-addiction
- Pain treatment
- Analgesic
- Opioid efficacy
- Acupuncture
- Meditation
- Marijuana pain
- Homeopathy

Once these results were returned, I reviewed the abstracts, study description, or results (evidence summary) to determine whether each study generally addressed my questions.

### **3.3.3 Step 3: Critical appraisal of evidence for validity, clinical relevance, and applicability**

First, the researcher must consider the type of study returned. Different guidelines may be used to critically appraise different types of studies. I used each of these, where appropriate, to inform my analysis.

#### **3.3.3.1 Individual Studies**

Questions for evaluating the results of an individual study:<sup>14</sup>

- Was the study randomized? Was the randomization concealed?
- Was follow-up sufficiently long and complete?
- Were all patients analyzed in the groups to which they were analyzed?
- Were patients and clinicians blinded to the treatment?
- Were groups treated equally apart from the experimental therapy?

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<sup>14</sup> Sackett DL, Straus SE, Richardson WS, Rosenberg W, Haynes RB. Evidence-Based Medicine: How to Practice and Teach EBM. 2nd Edition. Edinburgh, UK: Churchill Livingstone; 2000.

- Were groups similar at the start of the trial?

Once an individual study has been evaluated and the results deemed valid, the importance of the results may be evaluated by asking two questions:<sup>15</sup>

- What is the magnitude of the treatment effect?
- How precise is the estimate of the treatment effect?

For qualitative differences in treatment efficacy between subgroups, it is advised these differences only be considered important when the answer to all four of the following questions is yes:<sup>16</sup>

- Does it make biological and clinical sense?
- Is the qualitative difference both clinically and statistically significant?
- Was the difference hypothesized before the study began (rather than the product of dredging the data) and has it been confirmed in other independent studies?
- Was it one of just a few subgroup analyses carried out in the study?

Finally, the EBM practitioner must ask whether the important results of a valid, individual study are applicable to the particular problem or patient at hand.

### **3.3.3.2 Systematic Reviews**

Questions for evaluating the results of a systematic review:<sup>17</sup>

- Is this a systematic review of randomized trials?
- Does this systematic review have a “methods” section that describes:
  - Finding and including all relevant trials
  - How the validity of the individual studies was assessed?
- Were the results consistent from study to study?
- Were individual patient data in the analysis? Or was aggregate data used?

Once a systematic review has been evaluated and the results deemed valid, the importance of the results may be evaluated by asking two questions:<sup>18</sup>

- What is the magnitude of the treatment effect?
- How precise is the treatment effect?

Finally, the EBM practitioner must ask whether the important results of a valid systematic review are applicable to the particular problem or patient at hand.

### **3.3.3.3 Evidence of Harm**

Questions for evaluating the validity of evidence of harm by a treatment:

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<sup>15</sup> Ibid.

<sup>16</sup> Ibid.

<sup>17</sup> Ibid.

<sup>18</sup> Ibid.

- Were there clearly defined groups of patients, similar in all important ways other than exposure to the treatment (or other suspected cause)?
- Were treatments/exposures and clinical outcomes measured in the same ways in both groups? Was the assessment of outcomes either blinded to exposure or objectively measured?
- Was the follow-up of the study patients sufficiently long (for the outcome to occur and complete)?
- Do the results of the harm study fulfill some of the diagnostic considerations for causation?
  - Did exposure precede the outcome?
  - Is there a dose-response gradient?
  - Is there positive evidence from a “dechallenge-rechallenge” study?
  - Is the association consistent from study to study?
  - Does the association make biological sense?

Once the evidence of harm has been evaluated and deemed valid, the importance of the evidence may be evaluated by asking two questions:<sup>19</sup>

- What is the magnitude of the association between exposure and harm?
- How precise is the association between exposure and harm?

Finally, the EBM practitioner must ask whether the evidence of harm is applicable to the particular problem or patient at hand.

### ***3.3.3.4 Guidelines for Levels of Evidence***

Some EBM practitioners have created guidelines for categorizing and grading levels of evidence.

Canadian Task Force on the Periodic Health Examination’s Levels of Evidence:<sup>20</sup>

II.2
III

<sup>19</sup> Ibid.

<sup>20</sup> Adapted from Canadian Task Force on the Periodic Health Examination. The periodic health examination. Can Med Assoc J 1979;121:1193-254

Levels of Evidence from Sackett:<sup>21</sup>

IV	His
V	Ca

Levels of Evidence for Therapeutic Studies:<sup>22</sup>

4
5

<sup>21</sup> Adapted from Sackett DL. Rules of evidence and clinical recommendations on the use of antithrombotic agents. Chest 1989;95:2S–4S

<sup>22</sup> From the Centre for Evidence-Based Medicine, <http://www.cebm.net>.

Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence:<sup>23</sup>



\* Level ma  
studies, or

\*\* As alwa

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<sup>23</sup> OCEBM Levels of Evidence Working Group. "The Oxford 2011 Levels of Evidence". Oxford Centre for Evidence-Based Medicine.  
<http://www.cebm.net/index.aspx?o=5653>

As shown above, grading systems generally categorize systematic reviews of randomized control trials as the gold standard of evidence, followed by individual randomized control trials. The agencies which promulgate these grading systems often recognize that simplistic hierarchies ignore cases where observational studies, case-series, or even anecdotal evidence can provide definitive evidence and have made efforts to add greater nuance and flexibility to their grading scales.<sup>24,25</sup> GRADE guidelines also outline factors that may increase or decrease the strength of evidence from a particular study.<sup>26,27</sup> The GRADE factors which may decrease confidence in evidence are risk of bias, imprecision, inconsistency, indirectness, and publication bias. The GRADE factors which may increase confidence in evidence are large magnitude of effect, dose-response gradient, and cases where all plausible biases would decrease the magnitude of effect.<sup>28</sup>

Sackett (1997) cautioned against a “one-size-fits-all” approach to sources of evidence, but emphasized the important of randomized trials for assessing treatments:<sup>29</sup>

*...in terms of study designs, evidence-based medicine is not restricted to randomized trials and meta-analyses. It involves tracking down the best external evidence with which to answer our clinical questions. To find out about the accuracy of a diagnostic test, its practitioners seek likelihood ratios, sensitivities, and specificities derived from proper cross-sectional studies of patients clinically suspected of harboring the relevant disorder, not a randomized trial. For a question about prognosis, they search for multivariate prediction rules generated from proper follow-up studies of patients assembled at a uniform, early point in the clinical course of their disease. Also, sometimes the evidence will come from the basic sciences such as genetics or immunology. **It is when asking questions about therapy that the practitioners of evidence-based medicine avoid the non-experimental approaches, because these routinely lead to false-positive conclusions about efficacy. Because the randomized trial, and especially the systematic review of several randomized trials, is so much more likely to inform clinicians and so much less likely to mislead them, it has become the "gold standard" for judging whether a treatment does more good than harm.** [Emphasis added.]*

<sup>24</sup> OCEBM Levels of Evidence Working Group. "Background document: Explanation of the 2011 Oxford Centre for Evidence-Based Medicine (OCEBM) Levels of Evidence." Oxford Centre for Evidence-Based Medicine. <http://www.cebm.net/index.aspx?o=5653>

<sup>25</sup> Guyatt GH, Oxman A, Vist G, Kunz R, Falck-Ytter Y, Alonso-Coello P, et al. GRADE an emerging consensus on rating quality of evidence and stren. Br Med J. 2008;336(7650):924–6.

<sup>26</sup> Ibid.

<sup>27</sup> <https://bestpractice.bmj.com/info/us/toolkit/learn-ebm/what-is-grade/>

<sup>28</sup> Guyatt GH, Oxman AD, Sultan S, Glasziou P, Akl EA, Alonso-Coello P, et al. GRADE guidelines: 9. Rating up the quality of evidence. Journal of clinical epidemiology. 2011;64(12):1311-6.

<sup>29</sup> Sackett DL. Evidence-based medicine. *Semin Perinatol [Internet]*. 1997 Feb 1 [cited 2019 Feb 28];21(1):3–5. Available from: <https://www.sciencedirect.com/science/article/pii/S0146000597800134>

### 3.3.3.5 Evaluation of Funding Source and Conflicts of Interest

In addition to the factor reviewed above, funding source and conflicts of interest should be reviewed and considered for all studies. In their paper “How evidence-based medicine is failing due to biased trials and selective publication,” EBM practitioners Every-Palmer and Howick reached the following conclusions about the effect of industry funding on EBM practice:<sup>30</sup>

*We argue EBM's indiscriminate acceptance of industry-generated 'evidence' is akin to letting politicians count their own votes. Given that most intervention studies are industry funded, this is a serious problem for the overall evidence base. Clinical decisions based on such evidence are likely to be misinformed, with patients given less effective, harmful or more expensive treatments.*

The authors also provide a list of examples of methods for pharmaceutical companies to get the results they want from clinical trials:<sup>31,32</sup>

- Conduct a trial of your drug against a treatment known to be inferior.
- Trial your drugs against too low a dose of a competitor drug.
- Conduct a trial of your drug against too high a dose of a competitor drug (making your drug seem less toxic).
- Conduct trials that are too small to show differences from competitor drugs.
- Use multiple end points in the trial and select for publication those that give favorable results.
- Do multicenter trials and select for publication results from centers that are favorable.
- Conduct subgroup analyses and select for publication those that are favorable.
- Present results that are most likely to impress – for example, reduction in relative rather than absolute risk.

Every-Palmer and Howick recommend adopting industry bias as a factor in guidelines for evaluating levels of evidence:<sup>33</sup>

*Evidence-ranking schemes need to be modified to take the evidence about industry bias into account. There are already mechanisms within EBM evidence-ranking schemes to up- or downgrade evidence based on risk of bias. For example, the Grading of Recommendation Assessment, Development and Evaluation (GRADE) system allows for upgrading observational evidence demonstrating large effects, and downgrading randomized trials for failing to adequately conceal allocation (and various other factors) [65]. However,*

<sup>30</sup> Every-Palmer S, Howick J. How evidence-based medicine is failing due to biased trials and selective publication. *J Eval Clin Pract.* 2014;20(6):908–14.

<sup>31</sup> Ibid.

<sup>32</sup> Smith, R. (2005) Medical journals are an extension of the marketing arm of pharmaceutical companies. *PLoS Medicine*, 2 (5), e138.

<sup>33</sup> Every-Palmer S, Howick J. How evidence-based medicine is failing due to biased trials and selective publication. *J Eval Clin Pract.* 2014;20(6):908–14.



*currently such schemes are agnostic to the origins of evidence and do not expressly recognize the high risk of bias when the producers of evidence have an invested interest in the results. **It would be easy to introduce an evidence quality item based on whether a trial was conducted or funded by a body with a conflict of interest. If so, the evidence could be downgraded. Given the failure of current evidence-ranking schemes to detect and rule out industry-funding bias, this is a necessary step if EBM critical appraisal is to remain credible.***  
[Emphasis added.]

For these reasons, I included funding source and industry bias as one of the factors which would decrease my confidence in a particular source of evidence.

### 3.3.4 Step 4: Application of results in practice

This step speaks for itself. Once a critical analysis of the evidence has been completed, the findings can be applied to the situation at hand.

In this case, I applied my results in the form of my expert opinions.

### 3.3.5 Step 5: Evaluation of performance

Guidelines exist for self-evaluation of each of the previous steps of EBM practice.<sup>34</sup>

Self-evaluation for asking answerable questions:

- Am I asking any clinical questions at all?
- Am I asking well-formulated questions (based on the guidelines reviewed above)?
- Am I using a “map” to locate my knowledge gaps and articulate questions?
- Can I get myself “unstuck” when asking questions?
- Do I have a working method to save my questions for later answering?
- Am I modeling the asking of answerable questions for my learners?
- Am I writing any educational prescriptions in my teaching? Are they being “filled”?
- Are we incorporating question asking and answering into everyday activities?
- How well am I guiding my learners in their question asking?
- Are my learners writing educational prescriptions for me?

Not all of these questions applied to my practice of EBM in this context. Of those which did apply, I found that my performance was satisfactory.

Self-evaluation for finding the best external evidence:

- Am I searching at all?
- Do I know the best sources of current evidence for my clinical discipline?
- Have I achieved immediate access to searching hardware, software, and the best evidence for my clinical discipline?
- Am I finding useful external evidence from a widening array of sources?

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<sup>34</sup> Sackett DL, Straus SE, Richardson WS, Rosenberg W, Haynes RB. Evidence-Based Medicine: How to Practice and Teach EBM. 2nd Edition. Edinburgh, UK: Churchill Livingstone; 2000.

- Am I becoming more efficient in my searching?
- Am I using MeSH headings, thesaurus, limiters, and intelligent free text when searching MEDLINE?
- How do my searches compare with those of research librarians or other respected colleagues who have a passion for providing best current patient care?

I found that my performance was satisfactory.

Self-evaluation for critically appraising the evidence for its validity and potential usefulness:

- Am I critically appraising external evidence at all?
- Are the critical appraisal guides becoming easier for me to apply?
- Am I becoming more accurate and efficient in applying some of the critical appraisal measures?
- Am I creating any CATS (critically appraised topics)?

Not all of these questions applied to my practice of EBM in this context. Of those which did apply, I found that my performance was satisfactory.

Self-evaluation for applying results in practice:

- Am I integrating my critical appraisals into my practice at all?
- Am I becoming more accurate and efficient in adjusting some of the critical appraisal measures to fit my individual patients?
- Can I explain and resolve disagreements about management decisions in terms of this integration?
- Have I conducted any clinical decision analyses?
- Have I carried out any audits of my diagnostic, therapeutic, or other EBM performance?

Not all of these questions applied to my practice of EBM in this context. Of those which did apply, I found that my performance was satisfactory.

## 4 DEFINITIONS

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### 4.1 CHRONIC PAIN

As referred to herein, “chronic pain” is pain that has persisted after reasonable medical efforts have been made to relieve the pain or cure its cause and that has continued, either continuously or episodically, for longer than three continuous months.

See **Exhibit B.16**.

### 4.2 ADDICTION

As referred to herein, “addiction” is a cluster of behavioral, cognitive, and physiological phenomena that develop after repeated substance use and includes: a strong desire to take the drug, difficulties in controlling its use, persisting in its use despite harmful consequences, a higher priority given to drug use than to other activities and obligations, increased tolerance, and sometimes a physical withdrawal.

See **Exhibit B.367**.

### 4.3 TOLERANCE

As referred to herein, “tolerance” is the condition of a patient receiving, for one week or longer, at least 60 mg oral morphine/day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oral oxymorphone/day, or an equianalgesic dose of another opioid.

See **Exhibit B.15**.

### 4.4 THE “VENTURE”

As referred to herein, the “Venture” refers to all Defendants in the Opiate Litigation (including their associated individuals and/or organizations) acting in a concerted fashion separately or together to effect a particular objective.

See **Exhibit B.473**.

### 4.5 ADDITIONAL DEFINITIONS

I use a number of industry specific terms. These are more fully defined in **Exhibit B.401**.

## 5 CAPSULE OF OPINIONS

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The “Venture” acted in concert to:

1. Undermine the risks of opioid addiction;
2. Expand the market for opioid use by:
  - a. Expanding the indications for use;
  - b. Increasing the amount of opioids approved for use; and
  - c. Manipulating the doctors’ perceptions of the relative risks, benefits and potency of opioids.
  - d. Capitalizing on doctor’s misperceptions of the relative risks, benefits and potency of opioids.
  - e. Recommending that opioids be used for chronic non-malignant pain.
  - f. Defining pain as a disease, and not a symptom;
3. Target inappropriate prescribers, including:
  - a. Those prescribers who were not knowledgeable in the use of potent opioids for the management of chronic non-malignant pain.
  - b. Those prescribers who were likely sources of abuse and diversion;
4. Circumvent prescribing physicians by marketing directly to consumers as well as health care professionals, formularies, medical and nursing schools and state medical boards to promote increased use of opioids;
5. Overstate the efficacy and appropriateness of opioid analgesics in the treatment of chronic non-malignant pain and fail to warn of the risk of hyperalgesia;
6. Create and establish the myths around dosing, including but not limited to,
  - a. Dose frequency is fixed;
  - b. Titration should only be upward;
  - c. There is no ceiling dose;
  - d. The half-life elimination is the same for every human being on Earth;
7. Strategically utilize third parties, including but not limited, to front groups, key opinion leaders, advocacy groups, unbranded promotion, professional societies, trade groups, company-sponsored non-drug specific promotion, and continuing education programs, to create the conditions necessary.

See below, **Point 6**, and **Exhibits** hereto attached, including **Exhibits B.7, B.18, B.68, B.337, B.369, and B.404**.

## 6 IN 2004, I WARNED ABOUT THE CRISIS; I WAS IGNORED

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In 2004, I told Purdue Pharma the following facts and opinions. I hold the same opinions today. Purdue ignored this documented misconduct and continued to mislead the medical community about the addiction potential of their opioid drugs and expanded the market to encourage use in patients for whom the drugs' risks exceeded their benefits. In addition, after I described these problems to them, Purdue marketed a new opioid, Palladone, whose risks outweighed its benefits. <https://www.fda.gov/Drugs/DrugSafety/ucm129288.htm>

1. OxyContin is a Schedule II narcotic which was approved by the Food and Drug Administration in 1995. The main ingredient in OxyContin is oxycodone, which is a synthetic, morphine-like substance. **The drug was originally marketed for the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days, like cancer pain.** However, Purdue Pharma has aggressively marketed OxyContin through an advertising campaign that misled health providers and the public about the dangers of OxyContin. In many ways, Purdue's marketing strategy was formulated to assuage the disquiet of patients and physicians regarding the risks of abuse, diversion, addiction and death by overdose of OxyContin. Purdue Pharma developed the marketing piece "Myths about Opioids" to overcome the obstacle of physicians fearing that putting their patients on an opioid like OxyContin could cause them to become addicted. One of Purdue's "myths" was "Opioid addiction (psychological dependence) is an important clinical problem in patients with moderate to severe pain treated with opioids."<sup>35</sup> In actuality, the myth wasn't the risk of addiction, but the evidence they used to dispel this "myth."
2. As a practicing physician who had an active primary care practice, Purdue's information on OxyContin, as provided in the *Physicians Desk Reference* gave me the impression that in general, patients would not become addicted to OxyContin if it were prescribed to them for pain. Unfortunately, I first became aware of the serious problems associated with OxyContin use through experiences with my patients which contradicted the promising scenario Purdue provided in its marketing materials and "warnings." My patient experience revealed that addiction was a serious consequence of the prescription of OxyContin for pain.
3. A review of the product labeling for OxyContin from 1999 to 2001 underscores Purdue's failure to warn adequately regarding abuse or addiction. Some of the major inadequacies

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<sup>35</sup> "Dispelling Myths about Opioids," Purdue Pharma.

of the labels comprise omissions of pertinent information and misrepresentations about the characteristics of OxyContin. I provide some examples below.

The omissions include:

- a. Purdue failed to include “prior drug addiction” under the “Contraindications section” for the use of OxyContin. Instead, under a different section called “Use in Drug Abuse and Addiction” the statement was limited to “[OxyContin] has no approved use for the management of addictive disorders,”<sup>36,37,38</sup>
- b. Purdue failed to include the risk of addiction in the label’s “Warning” or “Precautions” sections;<sup>39</sup>
- c. Purdue omitted from the “Information for Patients/Caregivers” a warning that repeated administration could lead to addiction;<sup>40</sup>
- d. Purdue failed to list any of the symptoms of opioid withdrawal;<sup>41</sup>

The misrepresentations include:

- e. Purdue told physicians that “delayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug.”<sup>42</sup> This is unsupported by any study and in fact while it is true that OxyContin has a slower release component, OxyContin also has a fast release component. “OxyContin Tablets exhibit a biphasic absorption pattern with two apparent absorption half times of 0.6 and 6.9 hours, which describes the initial release of oxycodone from the tablet followed by a prolonged release.”<sup>43</sup> Therefore, if delayed release reduced the likelihood of addiction then this drug would increase the risk of addiction.

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<sup>36</sup> *Physicians’ Desk Reference*, OxyContin Package Insert, 53<sup>rd</sup> ed. Montvale, NJ: Thompson PDR, 1999: 2572.

<sup>37</sup> *Physicians’ Desk Reference*, OxyContin Package Insert, 54<sup>th</sup> ed. Montvale, NJ: Thompson PDR, 2000:2539.

<sup>38</sup> *Physicians’ Desk Reference*, OxyContin Package Insert, 55<sup>th</sup> ed. Montvale, NJ: Thompson PDR, 2001.

<sup>39</sup> *Physicians’ Desk Reference*, OxyContin Package Insert, 1999, 2000 and 2001.

<sup>40</sup> *Ibid.*

<sup>41</sup> *Ibid.*

<sup>42</sup> *Ibid.*

<sup>43</sup> *Physicians’ Desk Reference*, OxyContin Package Insert, 57<sup>th</sup> ed. Montvale, NJ: Thompson PDR, 2003, 2852.

- f. Purdue stated that “tolerance and physical dependence in pain patients are not signs of psychological dependence.”<sup>44</sup> This is not true. Tolerance and physical dependence to a drug are typical, hallmark, diagnostic symptoms of substance dependence. *The Diagnostic and Statistical Manual of Mental Disorders* describes the criteria for substance dependence which include both tolerance and withdrawal. “Criteria for Substance dependence: (1) Tolerance, as defined by either of the following: (a) a need for markedly increased amounts of the substance to achieve intoxication or desired effect (b) markedly diminished effect with continued use of the same amount of the substance. (2) withdrawal, as manifested by either of the following: (a) the characteristic withdrawal syndrome for the substance (b) the same (or a closely related) substance is taken to relieve or avoid withdrawal symptoms.”<sup>45</sup>
4. The inadequacy of the OxyContin warning label is further underscored when it is compared to other addictive oral, controlled-release opioid analgesics containing morphine sulfate, MS Contin (Purdue Frederick) and OraMorph SR (Roxane). Both of these are marketed as controlled-release 12-hour pain control products like OxyContin and are Schedule II drugs with the same abuse liability as OxyContin. However, their labels are strikingly different, even though Purdue authored both the MS Contin and OxyContin labels.
5. Unlike the OxyContin label, the labels for MS Contin and OraMorph SR state that the product may cause addiction upon repeated use. The MS Contin label states that “psychological and physical dependence may develop upon repeated administration.”<sup>46</sup> The OxyContin label does not address issues related to psychological and physical dependence. The OraMorph SR (Roxane) label acknowledges the addiction risk even more clearly: “Morphine is the most commonly cited prototype for a narcotic substance that possesses an addiction-forming or addiction-sustaining liability. A patient may be at risk for developing dependence to morphine if used improperly or for overly long periods of time.”<sup>47</sup> Unlike the OraMorph label, OxyContin fails to alert physicians that, “Individuals with a history of opioid or other substance abuse or dependence, being more apt to respond to euphorogenic and reinforcing properties of morphine, would be considered to be at greater risk.”

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<sup>44</sup>Physicians’ Desk Reference, OxyContin Package Insert, 1999, 2000 and 2001.

<sup>45</sup> *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*. Washington, D.C.: The American Psychiatric Association, 1994: 181.

<sup>46</sup> Physicians’ Desk Reference, MS Contin Package Insert, 57<sup>th</sup> ed. Montvale, NJ: Thompson PDR, 2003, 2835.

<sup>47</sup> Physicians’ Desk Reference, OraMorph Package Insert, 56<sup>th</sup> ed. Montvale, NJ: Thompson PDR, 2002, 3063.



6. Also, unlike the OxyContin label, the OraMorph SR label does not emasculate statements regarding addictive potential by citing the product's "delayed absorption" characteristics. Unlike the OxyContin label, the OraMorph SR label does not minimize addiction concerns by proclaiming that "reports" of addiction are "rare." Purdue claimed that reports of addiction were rare before the drug was marketed; however, Purdue never performed any tests for addiction in its pre-market trials and health care providers could not make "reports" before Purdue sold the drug. In fact, soon after Purdue marketed the drug reports of addiction became all too common. They were so common in fact, that local newspapers began to report this problem in 1999. A search of LexisNexis revealed hundreds of press reports by 2001. There were not a comparable number of press reports for either MS Contin or OraMorph SR. In comparison to OxyContin, reports of addiction from other comparable drugs were "rare."
7. See attached table for further comparisons between the OxyContin, MS Contin and Percocet package inserts. (for table, see **Exhibit B.455**)
8. Purdue Pharma's own internal reports highlight problems with prescription drug abuse back to 2001. In 2001, a Purdue newsletter called "@purdue" included an article entitled, "A Busy Schedule for Dr. Haddox Produces Some Balanced Media." (See attached as Exhibit 1.) The article describes how Purdue has sent one of their most prominent physicians, Dr. Haddox, to the Appalachian States, "visiting the communities most affected by the abuse and diversion of OxyContin Tablets." Purdue reported that over a seven-month period, Dr. Haddox was on the road for 122 days dealing with "reports" and abuse of OxyContin. As a practicing physician, I would have wanted to know that one of Purdue's head doctors was traveling for 122 days dealing with issues of drug addiction related to OxyContin use. This would have allowed me to gauge the extent of the problem and would have allowed me to place the "rare reports" of addiction statement in perspective.
9. Beginning with the launch of the drug in 1996 Purdue's OxyContin physician-directed promotional pieces, including advertisements, brochures, and videos, asserted that, "less than 1% of patients taking opioids actually become addicted."<sup>48</sup> They also asserted that the development of addiction to opioid medication is "rare," and classify as "myth" that "opioid addiction (psychological dependence) is an important clinical problem in patients

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<sup>48</sup> "Dispelling Myths about Opioids," Purdue Pharma.

with moderate to severe pain treated with opioids."<sup>49,50</sup> These statements are wrong and/or unsupported by any scientific evidence.

10. Purdue Pharma supports and maintains a website which discusses pain and promotes its product. Unfortunately, it also uses this site to misinform health care providers and patients about the risks of use of OxyContin. The website is called, "Partners Against Pain," and includes articles such as "A Guide to Your New Pain Medication and How to Become a Partner Against Pain."<sup>51</sup> This article followed the "Frequently Asked Questions" format and asked, "Aren't opioid pain medications like OxyContin Tablets "addicting"? Even my family is concerned about this." Purdue proffered the following mischaracterization of addiction: "Drug addiction means using a drug to get "high" rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful. True addiction rarely occurs when opioids are being used properly under medical supervision to relieve pain." The "guide to patients" misleads patients into believing that their motivation for taking OxyContin (i.e., for pain instead of to "get high") is the sole determinant of whether they are, or will become, addicted to their pain medication.
  
11. In 2001, in another question and answer section of the website, under the heading "Patient/Caregiver", Partners against Pain declared: "When you feel pain, your pain is real... Remember: You have every right to ask [doctors and nurses] to help you relieve the pain as much as possible." This answer is self-serving and scientifically flawed. Medical literature notes that addiction pain and physiological pain overlap, and separating them presents unique challenges to the physician.<sup>52</sup> Addiction has been shown to make patients even more sensitive to pain - and thus more likely to request pain medications.<sup>53</sup> For example hyperalgesia, or diminished pain tolerance, is a sign of opioid withdrawal.<sup>54</sup> Patients who are dependent on opioid medication will sometimes undergo withdrawal symptoms that manifest as pain.<sup>55</sup> Implying that patients have a right to as much opioid as they wish minimizes the risk of addiction and perpetuates misinformation about addiction and pain perception.

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<sup>49</sup> Ibid.

<sup>50</sup> "I Got My Life Back," Partners Against Pain Brochure, Purdue Pharma, 1997, 8700300165.

<sup>51</sup> Partners Against Pain website, Available at:

<http://www.partnersagainstpain.com/html/main/index.htm>, Accessed on September 8, 2003.

<sup>52</sup> Compton, P., and Gebhart, G.F., "The Neurophysiology of Pain in Addiction," as seen in *The Principles of Addiction Medicine*, American Society of Addiction Medicine, (2<sup>nd</sup> ed. 1998), at 901, 912-914.

<sup>53</sup> Ibid. at 912.

<sup>54</sup> Ibid.

<sup>55</sup> Dickinson, "Use of Opioids to Treat Chronic, Noncancer Pain," *West J Med* 2000; 172:107, 111.

12. Purdue has also misled patients through their production of a pamphlet and informational video, “From One Pain Patient to Another,” which encouraged patients to doctor-shop to find providers who were most willing to prescribe narcotics. Purdue told patients, “Don’t be afraid about the things you’ve heard about these drugs [opioids],” and, “...find the right doctor”... “I think it is very unfortunate that so many physicians are reluctant to treat people like me, who have moderate chronic pain, with opioids.” Purdue thus disparaged the conservative and cautious prescribing practices of many responsible health practitioners. Again, Purdue actively misinformed and inadequately warned patients and physicians of the addiction risks and withdrawal symptoms associated with OxyContin.
13. Purdue has centered its promotional and marketing focus for OxyContin on the twice a day, every 12-hour dosing schedule. For example, when OxyContin was first introduced, Purdue stated that OxyContin offered a “significant advantage” because “unlike short-acting pain medications, which must be taken every 3 to 6 hours—often on an “as needed basis,” OxyContin tablets are taken every 12 hours, providing smooth and sustained pain control all day and all night.” Purdue’s 1998 OxyContin Budget Plan describes the importance of q12 dosing to sales, “Our marketing research indicates that the most important feature of OxyContin tablets, beyond the familiarity of oxycodone, is the q12h dosing schedule. In all seven pre-launch market research projects conducted among 626 healthcare professionals, this was the most compelling reason to prescribe the OxyContin Tablets.”<sup>56</sup>
14. However, Purdue’s marketing materials did not tell the entire story about the effective dose interval. In most clinical studies, OxyContin pain relief did not last for 12 hours. One of the first clinical trials showed that “half of the patients used IR (immediate release) oxycodone rescue almost daily,” revealing that the drug was not able to relieve pain for the full 12-hour dosing schedule.<sup>57</sup> Scientists at Purdue and other independent labs conducted a number of clinical tests that found that OxyContin did not relieve pain for 12 hours. (Hagen and Babul, 1997, Kaplan et al, 1998) Hagen and Babul showed that a significant percentage of patients on OxyContin and Hydromorph Contin required rescue analgesic. They reported that, “the percentage of rescue analgesic use in the first, second and third 4-hour periods representing the combined 12-hour dosing frequency of controlled release oxycodone... was 23.8%, 42.8% and 33.3% for controlled release oxycodone (OxyContin.)”<sup>58</sup> Kaplan et al similarly found that, “Among patients enrolled, after the amendment that allowed titration and rescue, 18 of 29 (62%) who received CR

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<sup>56</sup> Purdue Pharma Budget Plan, 1998, 4-41.

<sup>57</sup> Citron ML, Kaplan R, Parris WC et al, Long-Term Administration of Controlled-Release Oxycodone Tablets for the Treatment of Cancer Pain, *Cancer Investigation*, 1998;16(8): 563.

<sup>58</sup> Hagen NA, Babul N, Comparative Clinical Efficacy and Safety of a Novel Controlled-Release Oxycodone Formulation and Controlled-Release Hydromorphone in the Treatment of Cancer Pain, *Cancer*, 1997 Apr 1;79(7): 1432.

oxycodone needed at least one supplemental (rescue) dose... During the day, the median time to first rescue use was 4 hours for the CR (OxyContin) group.”<sup>59</sup>

Below is a summary of my opinions followed by a compilation of materials that I read reviewed or considered in compiling these opinions:

- 1) Purdue Pharma’s marketing was inappropriate and led to the abuse and misuse of OxyContin.
  - a) Purdue Pharma marketed OxyContin based on claims that were scientifically invalid or unproven. For example:
    - i) Purdue stated that “less than 1% of patients taking opioids actually become addicted” without any clinical data or valid scientific references.
      - (1) Purdue misinformed their sales representatives for OxyContin. When asked in a quiz during one of the sales representatives training sessions a question concerning the risk of iatrogenic addiction, Purdue told them the correct answer was “less than one percent.”
      - ii) Purdue said that iatrogenic addiction did not occur. Instead, they suggested that addiction only occurred when OxyContin was taken for illicit use. This is not true.
        - (1) William Gergely, a former Purdue district sales manager, told the Florida Attorney General that top sales officials had described OxyContin as “non-habit forming.” Sales representatives were taught to tell doctors that drug abusers would not be interested in OxyContin.
    - b) Purdue failed to include adequate warnings about the risk of addiction in their marketing materials. For example:
      - i) Purdue was cited by the FDA on numerous occasions for failing to include adequate warnings on advertisements. The FDA cited Purdue in May of 2000 for an advertisement stating that OxyContin can be used for arthritis pain when in actuality; OxyContin is not a first-line therapy for arthritis. Purdue was later cited in 2002 for two advertisements in the Journal of the American Medical Association that failed to describe and adequately present the possible risks of taking OxyContin.
    - c) OxyContin was recommended for inappropriate uses in marketing materials.
      - i) OxyContin was promoted for osteoarthritis sufferers and “weekend warriors” as a substitute for much weaker and safer pain medications.

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<sup>59</sup> Kaplan R, Parris WC, Citron ML, et al, Comparison of Controlled-Release and Immediate-Release Oxycodone Tablets in Patients with Cancer Pain. J Clin Oncol. 1998 Oct;16(10):3232-33.

- ii) Purdue manipulated the FDA approval process to assist in their marketing of OxyContin for treatment of osteoarthritis.
  - d) Purdue inappropriately marketed OxyContin for q12h dosing.
- 2) Purdue Pharma's warnings for Oxycontin were inappropriate and led to the abuse and misuse of OxyContin.
- a) Purdue's Product labeling for OxyContin fails to warn adequately regarding abuse or addiction.
    - i) Unlike similar drugs, OxyContin's patient package insert does not state that the product may cause addiction nor does it directly acknowledge the risk of narcotic dependence.
    - ii) Purdue Pharma's warning labels in Europe have much stronger warnings about addiction risk than their warning for United States patients.
  - b) Purdue used an FDA reprimand to expand the indications of OxyContin.
- 3) Purdue Pharma's information about dose and drug kinetics was wrong.
- a) Purdue Pharma had no data to support their patent claims that at a dose range of 10 to 40 every 12 hours, pain would be controlled in 90% of patients.
  - b) Purdue told physicians to prescribe OxyContin for q12 h dosing while Purdue had information that proved that most patients needed to be dosed at different intervals.
  - c) Purdue's dosing recommendation for Oxy IR drugs was based on marketing and other considerations, but not science. Purdue either recommended too frequent use of Oxy IR (q6) or used inadequate doses of IR in its OxyContin efficacy trials (q6 vs q4-6) or both.
  - d) Purdue has inaccurately made claims that "delayed absorption is believed to reduce the abuse liability of a drug." Purdue has no scientific evidence to prove this claim nor have they ever tested the merits of this claim.
  - e) Fundamental pharmacokinetic principles establish that, for a fixed total daily dose of OxyContin, peak plasma concentrations of oxycodone will be slightly lower, troughs in plasma concentrations of oxycodone will be slightly higher, and overall fluctuation in plasma concentrations will be slightly less, if OxyContin is administered every 8 hours than if OxyContin is administered every 12 hours. Purdue emphasized 12 hour dosing because the 12 hour dosing schedule represented a significant competitive advantage of OxyContin over other products.

- 4) Purdue failed to institute post market surveillance. They failed to use the IMS system to determine the location of “pill mills” or problem physicians. They failed to establish a monitoring system for addiction issues and failed to monitor emergency rooms for deaths and other serious side effects associated with drug use. They may have monitored internet chat rooms but failed to compile or organize this information.
- 5) Purdue greatly expanded the problem of drug addiction and caused or contributed to numerous deaths.

## **7 ADDITIONAL OPINIONS SINCE 2004**

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### **7.1 OPINION – 2004-7 INVESTIGATIONS INCLUDES OFF LABEL USES AND BAD REP BEHAVIOR FOR CEPHALON (TEVA)**

See Exhibit B.1 hereto attached.

### **7.2 OPINION – IN 2011, WALGREENS PHARMACISTS WERE OPENING SECOND PHARMACIES UNDER FAMILY MEMBERS' NAMES - UNDER PRESSURE TO FILL SCRIPTS NOT CONTROL THEM.**

See Exhibit B.2 hereto attached.

### **7.3 OPINION – WALGREENS SYSTEMS COULD BE MANIPULATED TO ALLOW STORES TO CIRCUMVENT QUANTITY RESTRICTIONS - KNOWN ISSUE - 'THIS IS HOW THE SYSTEM ALWAYS WORKED'.**

See Exhibit B.3 hereto attached.

### **7.4 OPINION – THE “VENTURE” BRIBED THE SAME DOCTORS TO OVERPRESCRIBE.**

See Exhibit B.4 hereto attached.

### **7.5 OPINION – THIS IS A DESCRIPTION OF DRUG PAYMENT FLOWS. I AGREE.**

See Exhibit B.5 hereto attached.

### **7.6 OPINION – ACTAVIS PRESCRIPTION COUPONS DO NOT WARN OF ADDICTION RISKS AND OFFER \$1200 OFF PER YEAR.**

See Exhibit B.6 hereto attached.

### **7.7 OPINION – THE “VENTURE” ACTED IN CONCERT TO UNDERMINE THE RISKS OF OPIOID ADDICTION.**

See Exhibit B.7 hereto attached.



**7.8 ALL FOR ONE AND ONE FOR ALL – THE “VENTURE” KNEW COLLECTIVE MARKETING INCREASED THE SIZE OF THE OPIOID PIE. SIMILARLY HAD ANY “VENTURE” MEMBER BROKEN RANKS, THE OPIOID MARKET WOULD HAVE SLOWED OR IF THE COMPLETE TRUTH WAS TOLD (NO EFFICACY AND HIGH ADDICTION RISK) THE MARKET WOULD HAVE CRASHED.**

See **Exhibit B.8** hereto attached.

**7.9 OPINION – THERE IS NO SCIENTIFICALLY AUTHORITATIVE EVIDENCE TO SUPPORT THE CLAIM THAT OPIOIDS ARE MORE EFFECTIVE THAN PLACEBO AND OTHER NON-OPIOID ALTERNATIVES FOR CHRONIC NON-MALIGNANT PAIN. THERE IS EVIDENCE THAT OPIOIDS ARE NO MORE EFFECTIVE THAN NON-OPIOID ALTERNATIVES FOR CHRONIC NON-MALIGNANT PAIN.**

See **Exhibit B.9** hereto attached.

**7.10 OPINION – I AGREE WITH ASHP (AMERICAN SOCIETY OF HOSPITAL PHARMACISTS) FORMULARY MANAGEMENT GUIDELINE**

See **Exhibit B.10** hereto attached.

**7.11 OPINION – PATIENTS TREATED WITH PRESCRIPTION OPIOIDS GET ADDICTED.**

See **Exhibit B.11** hereto attached.

**7.12 OPINION – CARDINAL FAILED TO TAKE ACTION FOR SUSPICIOUS ORDERS.**

See **Exhibit B.12** hereto attached.

**7.13 OPINION – COLLABORATION AND PEER INFLUENCE YIELD FORMULARY ACCESS FOR JANSSEN IN CLEVELAND**

See **Exhibit B.13** hereto attached.

**7.14 OPINION – COMPANIES SHOULD NOT MARKET NARCOTICS  
TO ELEMENTARY SCHOOL STUDENTS DIRECTLY OR INDIRECTLY.**

See **Exhibit B.14** hereto attached.

**7.15 OPINION – OPIOID TOLERANCE IS DEFINED AS:**

See **Exhibit B.15** hereto attached.

**7.16 OPINION – THE OHIO DEFINITION OF CHRONIC PAIN.**

See **Exhibit B.16** hereto attached.

**7.17 OPINION – DICTIONARY OF TERMS FOR WHOLESALER  
AGREEMENTS**

See **Exhibit B.17** hereto attached.

**7.18 OPINION – THE “VENTURE” ACTED IN CONCERT TO  
CIRCUMVENT PRESCRIBING PHYSICIANS BY MARKETING DIRECTLY  
TO CONSUMERS AS WELL AS HEALTH CARE PROFESSIONALS,  
FORMULARIES, MEDICAL AND NURSING SCHOOLS AND STATE  
MEDICAL BOARDS TO PROMOTE INCREASED USE OF OPIOIDS.**

See **Exhibit B.18** hereto attached.

**7.19 OPINION – DISCONTINUATION OF OPIOIDS REDUCES PAIN IN  
SOME PATIENTS**

See **Exhibit B.19** hereto attached.

**7.20 OPINION – DISTRIBUTORS DISPENSE IN DOCTORS' OFFICES  
AND CLINICS AND OFFER PRACTICE MANAGEMENT TOOLS.**

See **Exhibit B.20** hereto attached.

**7.21 OPINION – WALGREENS SOLUTION TO RED FLAGGED STORES WAS TO FIND A DISTRIBUTER WHO WOULD SELL TO THEM. ALL 3 WALGREENS DISTRIBUTOR FACILITIES FAILED TO IMPLEMENT SOM PROCEDURES.**

See Exhibit B.21 hereto attached.

**7.22 OPINION – THE “VENTURE” EXPANDED THE MARKET BY PROMOTING INAPPROPRIATE USE (LOW BACK SPASM) OF 3 YEARS DURATION WITH “SOME PAIN”.**

See Exhibit B.22 hereto attached.

**7.23 OPINION – THE “VENTURE” INTRODUCED THE CONCEPT OF THE “5TH VITAL SIGN” IN 1995, BUT LATER ALLOWED AMERICAN PAIN SOCIETY TO PROMOTE IT AS ITS OWN CREATION TO ENHANCE THE SALES OF OPIOIDS.**

See Exhibit B.23 hereto attached.

**7.24 OPINION – ABBOTT AND PURDUE TARGETED INAPPROPRIATE PHYSICIANS FOR USE OF OPIOIDS FOR CHRONIC PAIN.**

See Exhibit B.24 hereto attached.

**7.25 OPINION – AMERICAN PAIN FOUNDATION (“APF”) FRONTED FOR INDUSTRY TO INCREASE SALES.**

See Exhibit B.25 hereto attached.

**7.26 OPINION – “VENTURE” MEMBER ENDO FUNDED SEVERAL FRONT ORGANIZATIONS AND FUNDED NIH PUBLICATIONS AND VARIOUS “EDUCATIONAL” EVENTS.**

See Exhibit B.26 hereto attached.

**7.27 OPINION – CEPHALON’S ACTIQ WAS NOT INDICATED FOR, BUT WAS MARKETING OFF LABEL FOR MINOR PAIN.**

See Exhibit B.27 hereto attached.

**7.28 OPINION – CHRONIC LONG ACTING OPIOIDS ARE NOT INDICATED FOR TREATMENT OF OSTEOARTHRITIS, LOW BACK PAIN OR FIBROMYALGIA. OPIOIDS ARE NOT INDICATED AT ALL FOR RHEUMATOID ARTHRITIS OR FIBROMYALGIA.**

See Exhibit B.28 hereto attached.

**7.29 OPINION – CORPORATE INTEGRITY AGREEMENTS INDICATING THAT EACH OF THESE COMPANIES VIOLATED FDA RULES.**

See Exhibit B.29 hereto attached.

**7.30 OPINION – DOCTORS ON THE “VENTURE’S” PAYROLL ADMITTED THAT PSEUDOADDICTION DESCRIBES BEHAVIORS ‘CLEARLY CHARACTERIZED AS DRUG ABUSE’ AND PUT THE “VENTURE” AT RISK OF ‘SANCTIONING ABUSE.’**

See Exhibit B.30 hereto attached.

**7.31 OPINION – FORMULARY ACCESS IS KEY TO SALES - FORMULARY RESTRICTIONS HAD THE LARGEST INFLUENCE ON PRESCRIBING - PURDUE USED INFLUENCE TO GET OXYCONTIN ON MAYO CLINIC FORMULARY.**

See Exhibit B.31 hereto attached.

**7.32 OPINION – GETTING ON THE FORMULARY IN OHIO WAS IMPORTANT TO JOHNSON & JOHNSON.**

See Exhibit B.32 hereto attached.

**7.33 OPINION – THE BIG THREE DISTRIBUTOR DEFENDANTS USE GROUP PURCHASING ORGANIZATIONS (GPO’S).**

See Exhibit B.33 hereto attached.

**7.34 OPINION – HARMS OF LAO FOR CHRONIC PAIN OUTWEIGH THE RISKS.**

See Exhibit B.34 hereto attached.

**7.35 OPINION – IN 1997, PURDUE SECRETLY ACKNOWLEDGED THE ABUSE POTENTIAL OF OXYCONTIN. THEY EVEN KNEW THAT PATIENTS IN SHORT TERM STUDIES MANIFESTED BEHAVIOR SUSPICIOUS OF ADDICTION. PURDUE MARKETING SAID THE OPPOSITE CREATING ANTI-WARNINGS FALSELY REASSURING PRESCRIBERS THAT THE RISK OF ADDICTION WAS LOW OR ABSENT. IN ADDITION, PURDUE CHOSE TO NOT ESTABLISH A POST-MARKET ABUSE MONITORING SYSTEM TO EVALUATE THE EXTENT OF DIVERSION AND ADDICTION. PURDUE TREATED THE PRESCRIBERS AS MUSHROOMS.**

See Exhibit B.35 hereto attached.

**7.36 OPINION – IN 2004 I TOLD PURDUE THEY WERE DOING ALL THESE BAD THINGS. THEY CONTINUED TO DO THEM AND WORSE**

See Exhibit B.36 hereto attached.

**7.37 OPINION – FROM THE MID TO THE LATE 2000S, MARKETING SHIFTED TO INTEGRATED DELIVERY NETWORKS FROM INDIVIDUAL DOCTORS. AS A RESULT, DOCTORS ARE LOCKED INTO DRUG FORMULARIES.**

See Exhibit B.37 hereto attached.

**7.38 OPINION – OPIOID PRODUCTS SHOULD HAVE INCLUDED THE FOLLOWING WARNINGS**

See Exhibit B.38 hereto attached.

**7.39 OPINION – OPIOIDS ARE ADDICTIVE.**

See **Exhibit B.39** hereto attached.

**7.40 OPINION – PURDUE AND THE FDA CONCLUDED PALLADONE WAS LETHAL AND ITS RISKS OUTWEIGHED ITS BENEFITS BUT THEY DID NOT ISSUE A RECALL. PURDUE ISSUED RECALLS FOR DRUGS THAT WOULD NOT INJURE PATIENTS IF SOLD. THE NUMBER OF PATIENTS WHO DIED AS A RESULT IS UNKNOWN.**

See **Exhibit B.40** hereto attached.

**7.41 OPINION – PURDUE CLAIMS IT DISCONTINUED DISTRIBUTION OF 160 MG PILL IN APRIL 2001 BUT THIS REMAINED A DOSE IN THE LABEL. THUS, MEDICAL DOCTORS WOULD BE GIVEN THE MISIMPRESSION THAT 640 MG A DAY WAS AN APPROVED DOSE.**

See **Exhibit B.41** hereto attached.

**7.42 OPINION – PURDUE HIRED PROSTITUTES TO PROMOTE OXYCONTIN CR. THIS IS WRONG. PURDUE DISCUSSED VARIOUS WAYS TO CAPITALIZE ON SEX.**

See **Exhibit B.42** hereto attached.

**7.43 OPINION – PURDUE KNEW THAT OXYCONTIN HAD KILLED HUMAN BEINGS WHO TOOK INEFFECTIVE DOSES OF OXYCONTIN.**

See **Exhibit B.43** hereto attached.

**7.44 OPINION – PURDUE OXY CHAIN**

See **Exhibit B.44** hereto attached.

**7.45 OPINION – PURDUE USED SEX TO SELL. THIS IS WRONG.**

See **Exhibit B.45** hereto attached.

**7.46 OPINION – PURDUE VIOLATED ITS CIA**

See **Exhibit B.46** hereto attached.

**7.47 OPINION – SACKLER FRAUD BEGAN EARLY - SEE GLUTAVITE AD.**

See **Exhibit B.47** hereto attached.

**7.48 OPINION – THE WORDS DETAILED AND THOROUGH WERE DELIBERATELY REMOVED BY PURDUE FROM ITS ORDER MONITORING SYSTEM STANDARD OPERATING PROCEDURE AS PURDUE’S INTENT WAS NOT TO BE DETAILED AND THOROUGH.**

See **Exhibit B.48** hereto attached.

**7.49 OPINION – TEVA OFF LABEL MARKETING CREATED A REVERSE CORPORATE INTEGRITY AGREEMENT VIOLATION.**

See **Exhibit B.49** hereto attached.

**7.50 OPINION – TEVA OFF LABEL MARKETING TO NON-CANCER PATIENTS. CNMP PAIN IS NOT CANCER PAIN.**

See **Exhibit B.50** hereto attached.

**7.51 OPINION – THE “VENTURE” INFLUENCED WHO GUIDELINES AND THEN USED THEM TO UP SELL.**

See **Exhibit B.51** hereto attached.

**7.52 OPINION – THE “VENTURE” (INCLUDING TEVA) USED SEX TO SELL.**

See **Exhibit B.52** hereto attached.



**7.53 OPINION – THE FDA AGREES THAT THERE IS INSUFFICIENT EVIDENCE THAT THE RISK OF OPIOIDS OUTWEIGHS THE BENEFITS FOR TREATMENT OF CHRONIC NON-MALIGNANT PAIN.**

See Exhibit B.53 hereto attached.

**7.54 OPINION – PATIENT SAVINGS CARD PROGRAMS BOTH INCREASE AND PROLONG THE USE OF OPIOIDS.**

See Exhibit B.54 hereto attached.

**7.55 OPINION – WALGREENS CONTACTED OVER PRESCRIBING DOCTORS. THIS WAS A GOOD THING TO DO. TOO LITTLE TOO LATE HOWEVER.**

See Exhibit B.55 hereto attached.

**7.56 OPINION – WALGREENS KNEW PHARMACISTS COULD MANIPULATE QUANTITIES WITH THE AS400 SOFTWARE AND THEY KNEW THIS COULD RESULT IN CRIMINAL NOT JUST CIVIL ACTIONS.**

See Exhibit B.56 hereto attached.

**7.57 OPINION – ENDO, J&J, MALLINCKRODT AND TEVA AND PURDUE USED THE SAME COMPANY TO BUILD THEIR KEY OPINION LEADER (KOL) DATABASE.**

See Exhibit B.57 hereto attached.

**7.58 OPINION – IN 2001, THE “VENTURE” WAS ON NOTICE ABOUT THE RISKS INHERENT IN SALE OF OPIOIDS FOR CHRONIC PAIN AND TOOK STEPS TO UNDERMINE WARNINGS ABOUT THESE RISKS. I AGREE WITH HOLMBERG.**

See Exhibit B.58 hereto attached.

**7.59 OPINION – THE “VENTURE’S” “EVOLVED MESSAGE” WAS OR SHOULD HAVE BEEN KNOWN IN 1995.**

See Exhibit B.59 hereto attached.

**7.60 OPINION –THE FDA NEGOTIATED A DEAL WITH ROXANE ALLOWING ROXANE TO MARKET 15 AND 30 IR BASED ON A 505 (B2) IN EXCHANGE FOR ROXANE’S AGREEMENT TO NOT SELL SR.**

See Exhibit B.60 hereto attached.

**7.61 OPINION – OXYCONTIN DOSES ESCALATED RAPIDLY BECAUSE FOR MOST PATIENTS IT WAS NOT A 12 HOUR DRUG.**

See Exhibit B.61 hereto attached.

**7.62 OPINION – WHEN THE FDA TRIED TO LIMIT USE IN 2001 BY CHANGING THE LABEL FROM “MORE THAN A FEW DAYS” TO “EXTENDED PERIOD OF TIME”, THE “VENTURE” USED THIS LANGUAGE TO INCREASE THE MARKET.**

See Exhibit B.62 hereto attached.

**7.63 OPINION – DOCTORS ON THE “VENTURE’S” PAYROLL ADMITTED THAT PSEUDOADDICTION DESCRIBES BEHAVIORS ‘CLEARLY CHARACTERIZED AS DRUG ABUSE’ AND PUT THE “VENTURE” AT RISK OF ‘SANCTIONING ABUSE’ WHICH THEY DID.**

See Exhibit B.63 hereto attached.

**7.64 OPINION – DR. HADDOX AND PURDUE KNEW THAT PRESCRIBERS’ PERCEPTION OF THE RISK OF OPIOIDS WITH RESPECT TO ABUSE AND ADDICTION AMONG CHRONIC PAIN PATIENTS SHOULD BE INCREASED TWOFOLD.**

See Exhibit B.64 hereto attached.

**7.65 OPINION – THERE IS A DUTY TO MONITOR MARKETING.**

See Exhibit B.65 hereto attached.

**7.66 OPINION – “VENTURE” DISTRIBUTOR ABC WORKED WITH MANUFACTURES TO MARKET OPIOIDS.**

See Exhibit B.66 hereto attached.

**7.67 OPINION – FORMULARIES HAVE AN UNOFFICIAL “IF YOU ADD ONE YOU DELETE ONE” POLICY.**

See Exhibit B.67 hereto attached.

**7.68 OPINION – THE “VENTURE” ACTED IN CONCERT TO EXPAND THE INDICATIONS FOR USE OF OPIOIDS TO TREAT DISEASES FOR WHICH OPIOIDS WERE NOT INDICATED AND INCREASE THE DAILY DOSE AND DURATION OF USE OF OPIOIDS AND INCREASE THE USE OF LONG ACTING OPIOIDS.**

See Exhibit B.68 hereto attached.

**7.69 OPINION – THE “VENTURE” CORRUPTED THE FDA.**

See Exhibit B.69 hereto attached.

**7.70 OPINION –FDA FAILED TO PROPERLY REGULATE OPIOID INDICATIONS. WHEN THE FDA TRIED TO LIMIT USE IN 2001 BY CHANGING THE LABEL FROM “MORE THAN A FEW DAYS” TO “EXTENDED PERIOD OF TIME”, THE “VENTURE” USED THIS LANGUAGE TO INCREASE THE MARKET.**

See Exhibit B.70 hereto attached.

**7.71 OPINION – THE “VENTURE” USED THE REVOLVING DOOR  
FDA-INDUSTRY TO GET FAVORABLE RULINGS TO ENABLE THEM  
TO EXPAND THE MARKET TO PATIENTS WHO THEY AND THE FDA  
KNEW WERE INAPPROPRIATE FOR LONG TERM NARCOTICS.**

See Exhibit B.71 hereto attached.

**7.72 OPINION – THE HEAD OF THE DIVISION OF THE FDA  
RESPONSIBLE FOR OPIOIDS BEING APPROVED IS NOT A  
‘WATCHDOG’ TO THE AMERICAN PEOPLE.**

See Exhibit B.72 hereto attached.

**7.73 OPINION – THERE ARE FINANCIAL INTERLINKS BETWEEN  
THE WHOLESALERS (DISTRIBUTORS) AND EVERYONE ELSE IN THE  
CHAIN.**

See Exhibit B.73 hereto attached.

**7.74 OPINION – THE “VENTURE” TARGETED VULNERABLE  
ELDERLY AND HAD TO CONVINCE DOCTORS TO USE OPIOIDS ON  
NURSING HOME PATIENTS.**

See Exhibit B.74 hereto attached.

**7.75 OPINION – FORMULARY ACCESS IS KEY TO SALES.**

See Exhibit B.75 hereto attached.

**7.76 OPINION – FORMULARY VERY IMPORTANT**

See Exhibit B.76 hereto attached.

**7.77 OPINION – JANSSEN TARGETED YOUTH AND ATHLETES. JOHNSON & JOHNSON WAS PART OF PAIN COALITION WITH JANSSEN THAT TARGETED YOUTH. PAIN IS NOT A DISEASE. JOHNSON & JOHNSON AND JANSSEN ENGAGED IN ACTIONS TARGETED AT DIRECTLY INFLUENCING POTENTIAL PATIENTS AND CHILDREN.**

See Exhibit B.77 hereto attached.

**7.78 OPINION – LIMITING THE INITIAL NUMBER OF PILLS DISPENSED REDUCES ABUSE. THE “VENTURE” SHOULD HAVE TOLD PRESCRIBERS THIS.**

See Exhibit B.78 hereto attached.

**7.79 OPINION – THERE IS NO SCIENTIFICALLY AUTHORITATIVE ESTIMATE OF THE NUMBER OF PEOPLE WHO EXPERIENCE CHRONIC NON-MALIGNANT PAIN. THE ORIGINAL 100 MILLION NUMBER WAS A MYTH BASED ON A HARRIS POLL FUNDED BY ORTHO-McNEIL. HERE IS NO AGREED DEFINITION OF “CHRONIC PAIN.” PHONE AND OTHER SURVEYS CANNOT ASSESS THIS QUESTION. TO ASSESS THIS QUESTION, PHYSICIANS NEED TO INTERVIEW SUBJECTS TO DETERMINE IF THE “PAIN” IS CAUSED BY WORK, PSYCHIATRIC OR SOCIAL ISSUES OR OTHER ACTIVITY (SPORTS) VS AN EPIPHENOMENON OF A PHYSICAL INJURY. FOR EXAMPLE, NO STUDY HAS EVALUATED THE IMPACT OF PATIENTS ADDICTED TO OPIOIDS USING “PAIN COMPLAINTS” TO ACQUIRE OPIOIDS ON THE ESTIMATES. NO STUDY HAS EVALUATED THE CULTURAL DIFFERENCES RELATED TO THE GENERATION OF “PAIN” COMPLAINTS. COMPARE FOR EXAMPLE ISRAEL OR ITALY TO FINLAND.**

See Exhibit B.79 hereto attached.

**7.80 OPINION – THE “VENTURE” HID THEIR FUNDING OF RESEARCH BY LAUNDERING THE MONEY THROUGH THIRD PARTIES.**

See Exhibit B.80 hereto attached.

**7.81 OPINION – THE “VENTURE” SHOULD HAVE KNOWN THAT HIGHER DOSES KILL AND WARNED ABOUT THIS.**

See **Exhibit B.81** hereto attached.

**7.82 OPINION – THE “VENTURE’S” MARKETING INFLUENCES DOCTORS.**

See **Exhibit B.82** hereto attached.

**7.83 OPINION – MALLINCKRODT AND WALGREENS AGREEMENTS INCLUDE CO-MARKETING.**

See **Exhibit B.83** hereto attached.

**7.84 OPINION – MARKETING IMPACTS ON SALES.**

See **Exhibit B.84** hereto attached.

**7.85 OPINION: MCKESSON AND PURDUE CO-MARKETED PURDUE DRUGS**

See **Exhibit B.85** hereto attached.

**7.86 OPINION – MCKESSON PUSHED OXYCONTIN**

See **Exhibit B.86** hereto attached.

**7.87 OPINION – MS CONTIN AND OXYCONTIN HAVE A SIMILAR CHEMICAL MAKEUP AND SHOULD HAVE SIMILAR WARNINGS. A COMPARISON OF THE OXYCONTIN AND MS CONTIN PACKAGE INSERTS SHOW AN AFFIRMATIVE “UNDERWARNING” BY PURDUE OF THE HEALTH RISKS OF OXYCONTIN.**

See **Exhibit B.87** hereto attached.

**7.88 OPINION – PURDUE DESTROYED INFORMATIONAL MATERIALS.**

See **Exhibit B.88** hereto attached.

**7.89 OPINION – PURDUE KNEW THAT INAPPROPRIATE PATIENTS WERE GETTING OXYCONTIN.**

See Exhibit B.89 hereto attached.

**7.90 OPINION – PURDUE’S INAPPROPRIATE MARKETING IS DESCRIBED HERE.**

See Exhibit B.90 hereto attached.

**7.91 OPINION – WALGREENS DEVELOPED AN INTERVENTION FOR OVER PRESCRIBING MEDICAL DOCTORS IN 2013.**

See Exhibit B.91 hereto attached.

**7.92 OPINION – WALGREENS GOOD FAITH DISPENSING POLICY PILOTS SHOW HIGH DOSE OPIATE PRESCRIBERS AVOIDING WALGREENS – SHIFT TO OTHER STORES.**

See Exhibit B.92 hereto attached.

**7.93 OPINION – PURDUE AND WALGREENS CIRCUMVENTED A DOJ PLEA DEAL**

See Exhibit B.93 hereto attached.

**7.94 OPINION – TEVA VIOLATIONS OF GOOD SALES AND MARKETING PRACTICES.**

See Exhibit B.94 hereto attached.

**7.95 OPINION – WALGREENS BAD CONDUCT EXAMPLES.**

See Exhibit B.95 hereto attached.

**7.96 OPINION – THE “VENTURE” GROSSLY MISLED DISTRIBUTORS AND PATIENTS WITH THE CLAIM THAT “FEAR OF ADDICTION IS EXAGGERATED” WITHOUT OFFERING SUPPORTING EVIDENCE.**

See Exhibit B.96 hereto attached.



**7.97 OPINION – TITRATION IS THE KEY FOR A “BIGGER BONUS” FOR THE “VENTURE” EVEN IF IT MEANS “ESCALATING DOSAGE AND NUMBER OF TABLETS”.**

See Exhibit B.97 hereto attached.

**7.98 OPINION – IN THE ONLY LONG-TERM STUDY OF HIGH DOSE OPIOID RX THERE WERE HIGH RATES OF ADDICTION**

See Exhibit B.98 hereto attached.

**7.99 OPINION – MARKETING WORKS FENTORA EXAMPLE RETURN ON INVESTMENT**

See Exhibit B.99 hereto attached.

**7.100 OPINION – HEALTHCARE DISTRIBUTION MANAGEMENT ASSN (HDMA NOW HDA) WAS RESPONSIBLE FOR SALE OF UNAPPROVED OPIOIDS**

See Exhibit B.100 hereto attached.

**7.101 OPINION – I AGREE WITH THE UNIVERSITY OF WASHINGTON SELF-ANALYSIS. THIS IS NOT ALWAYS THE CASE BUT IT WAS FOR THEM. “THEY SAY WHOEVER FUNDS YOUR ORGANIZATION OWNS IT!”**

See Exhibit B.101 hereto attached.

**7.102 OPINION – IMPACT HAD IMPACT**

See Exhibit B.102 hereto attached.

**7.103 IMPACT WAS “VENTURE’S” SUCCESSFUL EFFORT TO HAVE THE FDA ADOPT POOR EPIDEMIOLOGIC PRACTICES TO APPROVE OPIOIDS. IT WAS PAY TO PLAY AND PROBABLY VIOLATED ANT-TRUST LAWS AS WELL.**

See Exhibit B.103 hereto attached.

**7.104 OPINION – IRONICALLY THE UNDER TREATMENT OF  
AFRICAN AMERICANS AND HISPANICS PROTECTED THEM FROM  
OPIOID DEATHS**

See Exhibit B.104 hereto attached.

**7.105 OPINION – JANSSEN PARTICIPATED IN IMPACT PAY TO  
PLAY PROGRAM**

See Exhibit B.105 hereto attached.

**7.106 OPINION – JANSSEN VIOLATED ITS CORPORATE INTEGRITY  
AGREEMENT**

See Exhibit B.106 hereto attached.

**7.107 OPINION – THE DOJ RECOGNIZED THAT WALGREENS'  
DIVERSION PROBLEMS STEMMING FROM ITS JUPITER, FL  
DISTRIBUTION CENTER, IMPACTED OHIO USERS**

See Exhibit B.107 hereto attached.

**7.108 OPINION – MALLINCKRODT KNEW MARKETING INFLUENCED  
DOCTOR PRESCRIBING OF OPIOIDS**

See Exhibit B.108 hereto attached.

**7.109 OPINION – MANUFACTURERS USED WHOLESALERS AS  
CONDUIT FOR MARKETING**

See Exhibit B.109 hereto attached.

**7.110 OPINION – MCKESSON CONTROLLED MARKET SHARE OF  
VARIOUS OPIOIDS.**

See Exhibit B.110 hereto attached.

**7.111 OPINION – MCKESSON PROVIDED THE “VENTURE” BANG FOR THE BUCK IN TERMS OF ENHANCED SALES.**

See Exhibit B.111 hereto attached.

**7.112 OPINION – I AGREE WITH PURDUE’S ANALYSIS OF ITS MARKETING OBLIGATIONS. THEY VIOLATED THEM.**

See Exhibit B.112 hereto attached.

**7.113 OPINION – THE “VENTURE” ENCOURAGED SALES REPS TO PUSH DOCTORS TO “INDIVIDUALIZE THE DOSE” TO INCREASE PATIENTS’ DOSAGES OF OPIOIDS.**

See Exhibit B.113 hereto attached.

**7.114 OPINION – THE “VENTURE” FOUND THAT MARKETING WAS ESPECIALLY IMPORTANT TO SELL HIGHER DOSES OF OPIOIDS, SO THE “VENTURE” SPECIFICALLY FOCUSED ON MARKETING HIGH-DOSE OPIOIDS.**

See Exhibit B.114 hereto attached.

**7.115 OPINION – I AGREE WITH THE OIG EVALUATION OF PROMOTION OF PRESCRIPTION DRUGS THROUGH PAYMENTS AND GIFTS (OEI-01-90-00480; 8/91)**

See Exhibit B.115 hereto attached.

**7.116 OPINION – IN 2000, OXYCONTIN WAS IN 89% OF THE FORMULARIES IN OHIO**

See Exhibit B.116 hereto attached.

**7.117 OPINION – PALERMO – PURDUE ATTEMPTS TO SMOKE SCREEN THE FDA ABOUT RELEASE TIMES FOR OXYCONTIN.**

See Exhibit B.117 hereto attached.

**7.118 OPINION – THE “VENTURE” USED FOOD AND “VOUCHERS”  
TO SELL – TEVA’S CEPHALON**

See Exhibit B.118 hereto attached.

**7.119 OPINION – OPIOIDS ARE TOXIC.**

See Exhibit B.119 hereto attached.

**7.120 OPINION – 3RD PARTY MARKETING IS MOST EFFECTIVE.**

See Exhibit B.120 hereto attached.

**7.121 OPINION – AMERISOURCE BERGEN (“ABC”) WANTED TO  
‘LOW KEY’ (HIDE) ITS ASSOCIATION WITH PAIN CARE FORUM  
 (“PCF”).**

See Exhibit B.121 hereto attached.

**7.122 OPINION – ALL MARKETING SHOULD HAVE STATED DISEASES  
AND INJURIES THAT ARE NOT ‘MODERATE PAIN.’**

See Exhibit B.122 hereto attached.

**7.123 OPINION – ALLERGAN DATA DOES NOT PROVIDE EVIDENCE  
THAT ALLERGAN’S OPIOIDS WORK FOR CHRONIC NON-MALIGNANT  
PAIN.**

See Exhibit B.123 hereto attached.

**7.124 OPINION – ANY MARKETING OF ANY OPIOID FOR A SPECIFIC  
DISEASE IS “OFF LABEL”.**

See Exhibit B.124 hereto attached.

**7.125 OPINION – “VENTURE” MEMBER CEPHALON ENCOURAGED  
OVERUSE BY OFF LABEL MARKETING**

See Exhibit B.125 hereto attached.

**7.126 OPINION – “VENTURE” MEMBER JANSSEN ENGAGED IN A VARIETY OF ACTIVITIES TO UNDERMINE RISK OF ADDICTION AND INCREASE USE IN PATIENT WHERE USE WAS NOT OR CONTRAINDICATED. THEY ALSO USED FRONT GROUPS TO ASSIST.**

See **Exhibit B.126** hereto attached.

**7.127 OPINION – “VENTURE” MEMBER JANSSEN (JOHNSON & JOHNSON) ENGAGED IN A VARIETY OF ACTIVITIES TO UNDERMINE RISK OF ADDICTION AND INCREASE INAPPROPRIATE USE. THEY ALSO USED FRONT GROUPS TO ASSIST.**

See **Exhibit B.127** hereto attached.

**7.128 OPINION – “VENTURE” MEMBER MALLINCKRODT MISREPRESENTED PROPER DOSING TO ITS SALES REPRESENTATIVES.**

See **Exhibit B.128** hereto attached.

**7.129 OPINION – “VENTURE” MEMBER MCKESSON MARKETING OPIOIDS.**

See **Exhibit B.129** hereto attached.

**7.130 OPINION – “VENTURE” MEMBER TEVA USED MARKETING TO UNDERMINE ADDICTION RISK AND MARKET DIRECTLY TO PATIENTS.**

See **Exhibit B.130** hereto attached.

**7.131 OPINION – COCHRANE EVALUATIONS DO NOT WORK FOR SIDE EFFECTS.**

See **Exhibit B.131** hereto attached.

**7.132 OPINION – CONTROL OF INAPPROPRIATE DISPENSING DID NOT IMPACT ON PATIENT NEED FOR PAIN CONTROL.**

See **Exhibit B.132** hereto attached.

**7.133 OPINION – CUYAHOGA COUNTY RELIED ON ITS PHARMACY  
BENEFIT MANAGER TO DETERMINE ITS FORMULARY.**

See **Exhibit B.133** hereto attached.

**7.134 OPINION – DEA ALERTED WALGREENS ABOUT IT’S BAD  
PRACTICES AND A PHARMACIST’S DUTY.**

See **Exhibit B.134** hereto attached.

**7.135 OPINION – DISTRIBUTOR MARKETING DROVE SALES.**

See **Exhibit B.135** hereto attached.

**7.136 OPINION – ENDO SOUGHT TO INFLUENCE FORMULARY  
DECISIONS BY FINDING PEOPLE TO INFLUENCE.**

See **Exhibit B.136** hereto attached.

**7.137 OPINION – ENDO WAS EITHER TOO CHEAP TO ADD ITS OPIOID  
LABELS TO THE 2014 PDR OR COMPLETELY IRRESPONSIBLE FOR  
THIS FAILURE TO WARN DOCTORS OF ANY DATA CONCERNING THESE  
DANGEROUS DRUGS.**

See **Exhibit B.137** hereto attached.

**7.138 OPINION – “VENTURE” DISTRIBUTORS MARKETING OPIOIDS  
FOR MANUFACTURERS.**

See **Exhibit B.138** hereto attached.

**7.139 OPINION – ROXANE DID NOT PROVIDE SOUND SCIENCE TO  
THE FDA.**

See **Exhibit B.139** hereto attached.

**7.140 OPINION – FDA APPROVALS WERE NOT BASED ON SOUND SCIENCE PROVIDED BY PURDUE. EVEN THE SACKLERS AND PURDUE AGREE. SELLERS OF OXYCODONE SHOULD HAVE WARNED ABOUT HIGHER BLOOD LEVELS IN PEOPLE OLDER THAN 65.**

See Exhibit B.140 hereto attached.

**7.141 OPINION – FORMULARY ACCESS WAS CRUCIAL**

See Exhibit B.141 hereto attached.

**7.142 OPINION – FORMULARY ACCESS WAS/IS KEY TO SALES.**

See Exhibit B.142 hereto attached.

**7.143 OPINION – PURDUE’S DAVID HADDOX MADE MANY MISLEADING STATEMENTS TO THE PRESS, BLAMING THE VICTIM INSTEAD OF THE “VENTURE” FOR ADDICTION, MINIMIZING ADDICTION RISK, OVERDOSE RISK, OPIOIDS WERE SAFE AND EFFECTIVE [160 MG PILL AND PALLADONE REMOVED].**

See Exhibit B.143 hereto attached.

**7.144 OPINION – I ADOPT ALL OF DR. SAPER’S ANALYSIS OF THE HISTORY OF THE ORIGINS OF THE OPIOID EPIDEMIC**

See Exhibit B.144 hereto attached.

**7.145 OPINION – IN 1995, PURDUE AND ABBOTT KNEW THAT THERE WAS A PAIN CATEGORY BETWEEN MODERATE AND SEVERE BUT THEY NEVER DISCLOSED THIS.**

See Exhibit B.145 hereto attached.



**7.146 OPINION – IN 2001, THE FDA TOLD PURDUE NOT TO MARKET OXYCONTIN FOR TREATMENT OF OSTEOARTHRITIS OR LOW BACK PAIN BY ORDERING THEM TO DELETE SPECIFIC MENTION OF THESE DISEASES FROM THE LABEL. PURDUE TURNED THIS ORDER ON ITS HEAD, USING THE CHANGE TO REMOVE ALL LIMITS TO PRESCRIBING FOR ANY DISEASE WHERE THE PATIENT HAD MODERATE TO SEVERE PAIN.**

See **Exhibit B.146** hereto attached.

**7.147 OPINION – JICK SOLICITED MONEY FROM PURDUE**

See **Exhibit B.147** hereto attached.

**7.148 OPINION – MARKETING TO FIRST GRADERS IS UNETHICAL AND DISGUSTING.**

See **Exhibit B.148** hereto attached.

**7.149 OPINION – DOCTORS RESPOND TO MARKETING MESSAGES AND INCREASE PRESCRIPTIONS.**

See **Exhibit B.149** hereto attached.

**7.150 OPINION – NO ONE KNOWS WHAT CHRONIC PAIN IS AND THE DEFINITION IS A MOVING TARGET. IT IS NOT A DISEASE.**

See **Exhibit B.150** hereto attached.

**7.151 OPINION – NONE OF THE “VENTURE” EVER PERFORMED TOXICOLOGY OR SAFETY TESTING ON OXYCODONE.**

See **Exhibit B.151** hereto attached.

**7.152 OPINION – ONE OR MORE OF PURDUE’S “REDER’S DOC[TOR]S” AT THE FDA WERE ON THE FDA OXYCONTIN LABEL REVIEW TEAM IN 2001.**

See **Exhibit B.152** hereto attached.

**7.153 OPINION – OXYCONTIN WAS NOT APPROVED FOR PERSISTENT PAIN.**

See **Exhibit B.153** hereto attached.

**7.154 OPINION – PAIN TREATMENTS WERE A “GAIN LEADER” FOR OTHER DRUG SALES.**

See **Exhibit B.154** hereto attached.

**7.155 OPINION – PHARMACIES COULD HAVE REDUCED THE OPIOID PROBLEM.**

See **Exhibit B.155** hereto attached.

**7.156 OPINION – PHYSICIANS HAD THE MISIMPRESSION THAT OXYCONTIN WAS LESS POTENT THAN MS CONTIN. INSTEAD OF CORRECTING, THIS PURDUE TOOK ADVANTAGE OF THIS IGNORANCE TO ENCOURAGE INAPPROPRIATE USE OF OPIOIDS.**

See **Exhibit B.156** hereto attached.

**7.157 OPINION – PURDUE AGREES THAT MARKETING INCREASES SALES.**

See **Exhibit B.157** hereto attached.

**7.158 OPINION – PURDUE AND McKESSON WORKED IN CONCERT TO GET MISINFORMATION INTO THE STREAM OF COMMERCE.**

See **Exhibit B.158** hereto attached.

**7.159 OPINION – PURDUE AND WALGREENS CO-PROMOTED HYSINGLA EXTENDED RELEASE HYDROCODONE.**

See **Exhibit B.159** hereto attached.

**7.160 OPINION – PURDUE CLAIMED OXYCONTIN WAS EFFECTIVE HOWEVER DUE TO THE Q12 DOSING THIS TURNED OUT TO BE FALSE AND DOSE ESCALATION OCCURRED CREATING AN OPIOID ADDICTION MACHINE**

See **Exhibit B.160** hereto attached.

**7.161 OPINION – PURDUE CREATED DEMAND WITH WHOLESALERS.**

See **Exhibit B.161** hereto attached.

**7.162 OPINION – PURDUE DESTROYED DOCUMENTS.**

See **Exhibit B.162** hereto attached.

**7.163 OPINION – CARDINAL PROVIDED MARKETING TO MANUFACTURERS TO GET MESSAGES TO CVS.**

See **Exhibit B.163** hereto attached.

**7.164 OPINION – PURDUE DID NOT WANT TO REVEAL ITS BLAME THE VICTIM APPROACH TO ADDICTION FROM ITS DRUGS.**

See **Exhibit B.164** hereto attached.

**7.165 OPINION – PURDUE EXERTED INFLUENCE OVER NATIONAL ASSOCIATION OF STATE CONTROLLED SUBSTANCES AUTHORITIES (NASCSA).**

See **Exhibit B.165** hereto attached.

**7.166 OPINION – PURDUE FAILED TO CORRECT MISINFORMATION ABOUT OPIOIDS FOR HEADACHES.**

See **Exhibit B.166** hereto attached.

**7.167 OPINION – PURDUE HAD AN EARLY WARNINGS PROGRAM TO TRACK ADVERSE PUBLICITY. MOST OF THIS RELATED TO ABUSE ADDICTION ETC. PURDUE CREATED A PUBLIC RELATIONS PROGRAM TO RESPOND RATHER THAN AN INTENSIVE PROGRAM TO TRACK AND INFLUENCE DOCTORS TO STOP.**

See Exhibit B.167 hereto attached.

**7.168 OPINION – PURDUE HAD TO DEVELOP AND MAINTAIN AN INTENSIVE MARKETING PROGRAM TO HOLD MARKET SHARE AFTER THE INTRODUCTION OF GENERICS.**

See Exhibit B.168 hereto attached.

**7.169 OPINION – PURDUE ILLEGALLY MARKETED MS CONTIN FOR A YEAR WITHOUT APPROVAL.**

See Exhibit B.169 hereto attached.

**7.170 OPINION – PURDUE KNEW (1997) - INCREASING STOCK LEVELS CAN FOSTER DEMAND.**

See Exhibit B.170 hereto attached.

**7.171 OPINION – PURDUE KNEW DOCTORS WERE NOT USING OXY APPROPRIATELY.**

See Exhibit B.171 hereto attached.

**7.172 OPINION – PURDUE KNEW THAT PRIMARY CARE DOCTORS CARRY OUT THE DAY TO DAY MANAGEMENT OF PAIN PATIENTS. HOWEVER CHRONIC OPIOID THERAPY SHOULD ONLY BE MANAGED BY DOCTORS WHO HAD EXPERT EXPERIENCE IN TREATING PATIENTS WITH OPIOIDS FOR CHRONIC PAIN. (SEE 2015 LABEL) THE LATTER GROUP MAY HAVE INCLUDED FEW PRIMARY CARE DOCTORS.**

See Exhibit B.172 hereto attached.

**7.173 OPINION – PURDUE MADE MISLEADING CLAIMS ABOUT OXYCONTIN.**

See **Exhibit B.173** hereto attached.

**7.174 OPINION – PURDUE MARKETING MS CONTIN WITH FALSE AND MISLEADING CLAIMS AND IGNORED FDA CITATIONS TELLING THEM TO STOP.**

See **Exhibit B.174** hereto attached.

**7.175 OPINION – PURDUE MARKETING OXYCONTIN TO INAPPROPRIATE PATIENTS.**

See **Exhibit B.175** hereto attached.

**7.176 OPINION – PURDUE OFF LABEL MARKETING FOR ACUTE PAIN.**

See **Exhibit B.176** hereto attached.

**7.177 OPINION – PURDUE OFF LABEL MARKETING FOR MINOR PAIN.**

See **Exhibit B.177** hereto attached.

**7.178 OPINION – PURDUE OFF LABEL MARKETING FOR PATIENTS WHO SHOULD NOT HAVE BEEN TREATED WITH AN OPIOID.**

See **Exhibit B.178** hereto attached.

**7.179 OPINION – PURDUE PAID INDIVIDUALS TO PRESENT ON OPIOIDS.**

See **Exhibit B.179** hereto attached.

**7.180 OPINION – PURDUE PLANTED ARTICLES IN MEDIA TO UNDERMINE THE PUBLIC HEALTH RESPONSE TO THE OPIOID CRISIS. ASCH.ORG**

See **Exhibit B.180** hereto attached.

**7.181 OPINION – PURDUE PRESSURED PHARMACISTS TO SELL OXYCONTIN**

See **Exhibit B.181** hereto attached.

**7.182 OPINION – PURDUE REFUSED TO SPEND MONEY TO CHECK FOR SUSPICIOUS ORDERS.**

See **Exhibit B.182** hereto attached.

**7.183 OPINION – PURDUE REPLACES UNINSURED STOLEN OXY AND NATIONAL ACCOUNTS EDUCATED OVER 12,000 PHARMACISTS IN LIVE VENUES – ON THE "DUTY TO DISPENSE: "OVERCOMING UNCERTAINTY, DOUBT, AND FEAR."**

See **Exhibit B.183** hereto attached.

**7.184 OPINION – PURDUE SOUGHT TO HIDE INFORMATION ON MARKETING PITCHES AND RESPONSES. THIS VIOLATES THEIR OBLIGATION TO REPORT OVERUSE, PILL MILLS, ETC.**

See **Exhibit B.184** hereto attached.

**7.185 OPINION – PURDUE TRAINED WALGREENS PHARMACISTS.**

See **Exhibit B.185** hereto attached.

**7.186 OPINION – PURDUE USED FRONT GROUPS.**

See **Exhibit B.186** hereto attached.

**7.187 OPINION – PURDUE USED AMERICAN PAIN FOUNDATION (APF) TO UNDERMINE PROBLEMS RELATED TO ABUSE AND DIVERSION.**

See **Exhibit B.187** hereto attached.

**7.188 OPINION – PURDUE USED WHOLESALERS AND RETAILERS TO MARKET OPIOIDS.**

See **Exhibit B.188** hereto attached.

**7.189 OPINION – PURDUE WAS TRACKING DEATHS FROM OXYCONTIN BY 2000.**

See **Exhibit B.189** hereto attached.

**7.190 OPINION – PURDUE WORKED TO BLOCK DEA FROM RESTRICTING USE OF OPIOIDS TO PAIN SPECIALISTS. THIS WAS WRONG.**

See **Exhibit B.190** hereto attached.

**7.191 OPINION – PURDUE WORKED WITH MANAGED CARE ORGANIZATIONS AND USED REBATES TO DRIVE VOLUME. THIS IS CONCERTED ACTION TO DRIVE VOLUME.**

See **Exhibit B.191** hereto attached.

**7.192 OPINION – PURDUE’S ALLEGED ACTIONS TO ADDRESS ADDICTION WAS DRIVEN BY ITS DESIRE TO MAINTAIN MARKET SHARE AND UNDERMINE THE PUBLIC’S CONCERN ABOUT ADDICTION. THAT IS WHY PURDUE FOCUSED ITS EFFORTS ON BLAMING THE VICTIMS AND “CRIMINALS” RATHER THAN ITS OWN PRODUCT AND MARKETING PRACTICES.**

See **Exhibit B.192** hereto attached.

**7.193 OPINION – REBATES INCREASE PROFITS AND SALES AND WERE USED TO INFLUENCE PHARMACISTS.**

See **Exhibit B.193** hereto attached.



**7.194 OPINION – REINSTATEMENT REQUIRED BUYING CONDITIONS THAT WOULD INCREASE SALES.**

See **Exhibit B.194** hereto attached.

**7.195 OPINION – REVOLVING DOOR - DR. GOTTLIEB SUPPORTS IMPACT WHILE INVESTING IN PHARMACEUTICAL COMPANIES AND THEN BECOMES HEAD OF FDA.**

See **Exhibit B.195** hereto attached.

**7.196 OPINION – RICHARD SACKLER IS THE PABLO ESCOBAR OF THE NEW MILLENNIUM. I AGREE.**

See **Exhibit B.196** hereto attached.

**7.197 OPINION – TARGET RELAXED GOOD FAITH DISPENSING IN 2014.**

See **Exhibit B.197** hereto attached.

**7.198 OPINION – THE AMERICAN PAIN FOUNDATION (APF) REPEATED THE “VENTURE’S” LIES THAT OPIOIDS ARE NOT ADDICTIVE IF TAKEN AS DIRECTED AND PROVIDE “RELIEF,” NOT A “HIGH”.**

See **Exhibit B.198** hereto attached.

**7.199 OPINION – THE “VENTURE” USED FRONT GROUPS TO INCREASE SALES. IN THIS CASE ABC INSTRUCTS ENDO ON HOW TO USE FRONT GROUPS.**

See **Exhibit B.199** hereto attached.

**7.200 OPINION – THE “VENTURE” AGGRESSIVELY MARKETING OPIOIDS AS DRUGS TO “START WITH AND STAY WITH” DESPITE KNOWLEDGE OF ITS ADDICTIVE NATURE.**

See **Exhibit B.200** hereto attached.

**7.201 OPINION – THE “VENTURE” AND FDA HAD OFF THE RECORD CONVERSATIONS TO COORDINATE POLICY DECISIONS. HADDOX REPRESENTS 22 COMPANIES**

See Exhibit B.201 hereto attached.

**7.202 OPINION – THE “VENTURE” AND KEY OPINION LEADERS HELPED O’BRIEN REVISE THE DIAGNOSTIC AND STATISTICAL MANUAL (DSM) V TO CHANGE THE LANGUAGE OF THE OPIOID DISORDER FROM DEPENDENCE TO ADDICTION.**

See Exhibit B.202 hereto attached.

**7.203 OPINION – THE “VENTURE” CHANGED THE DIAGNOSTIC AND STATISTICAL MANUAL (DSM) LANGUAGE TO GIVE THE IMPRESSION THAT ADDICTION WAS INHERENT AND THUS NOT A CRITERIA FOR DEPENDENCE.**

See Exhibit B.203 hereto attached.

**7.204 OPINION – THE “VENTURE” CITES ‘MOST DOCTORS’ AS STATING THAT ‘PATIENTS TREATED WITH PROLONGED OPIOID MEDICINES USUALLY DO NOT BECOME ADDICTED.’ THERE IS NO EVIDENCE THAT ‘MOST DOCTORS’ SUPPORT THIS CLAIM.**

See Exhibit B.204 hereto attached.

**7.205 OPINION – THE “VENTURE” COULD HAVE IMPACTED ON MISUSE THROUGH PHARMACY INTERVENTION – GOOD FAITH DISPENSING PROGRAM EXAMPLE WALGREENS**

See Exhibit B.205 hereto attached.

**7.206 OPINION – THE “VENTURE” COULD HAVE TRACKED THE IMPACT OF ITS ACTIVITIES ON OFF-LABEL USE OF OPIOIDS. IT FAILED TO DO SO.**

See Exhibit B.206 hereto attached.

**7.207 OPINION – THE “VENTURE” CREATED MISINFORMATION ON ADDICTION RISK AND TREATMENT INDICATIONS.**

See **Exhibit B.207** hereto attached.

**7.208 OPINION – THE “VENTURE” CREATED THE ENTITY KNOWN AS, ‘PSEUDOADDICTION’ SEPARATE FROM ‘REAL ADDICTION’ TO DOCTORS AND INSTRUCTED DOCTORS TO INCREASE OPIOID DOSES IN THESE SITUATIONS.**

See **Exhibit B.208** hereto attached.

**7.209 OPINION – THE “VENTURE” DID NOT USE THESE SURVEY METHODS TO TRY TO STOP OVERPRESCRIBING.**

See **Exhibit B.209** hereto attached.

**7.210 OPINION – THE “VENTURE” FOCUSED ON FORMULARY APPROVALS.**

See **Exhibit B.210** hereto attached.

**7.211 OPINION – THE “VENTURE” HAD AT LEAST 3 APPROACHES TO FORMULARY PENETRATION.**

See **Exhibit B.211** hereto attached.

**7.212 OPINION – THE “VENTURE” HAD A COMPLETE LACK OF UNDERSTANDING OF ADDICTION. ADDICTION IS NOT A CRIME. ADDICTION UNLIKE “CHRONIC PAIN” IS A DISEASE.**

See **Exhibit B.212** hereto attached.

**7.213 OPINION – THE “VENTURE” HAD A VARIETY OF APPROACHES TO INCREASE OPIOID USE.**

See **Exhibit B.213** hereto attached.

**7.214 OPINION – THE “VENTURE” HAS THE “SELLING TOOLS” TO  
“KEEP PATIENTS ON OXYCONTIN LONGER AND AT HIGHER DOSES.”**

See Exhibit B.214 hereto attached.

**7.215 OPINION – THE “VENTURE” HEALTHCARE DISTRIBUTION  
MANAGEMENT ASSN (HDMA/HDA) MEMBERSHIP.**

See Exhibit B.215 hereto attached.

**7.216 OPINION – THE “VENTURE” INCLUDING DISTRIBUTORS  
MARKETED UNAPPROVED DRUGS.**

See Exhibit B.216 hereto attached.

**7.217 OPINION – THE “VENTURE” INFLUENCED NIH CANCER PAIN  
MANAGEMENT HANDBOOK TO FACILITATE INCREASED USE OF  
OPIOIDS IN THIS CASE, ESPECIALLY ENDO’S PRODUCT.**

See Exhibit B.217 hereto attached.

**7.218 OPINION – THE “VENTURE” INFLUENCED THE SELECTION OF  
THE PRESIDENT OF THE AMERICAN PAIN FOUNDATION.**

See Exhibit B.218 hereto attached.

**7.219 OPINION – THE “VENTURE” INSTRUCTED ITS SALES REPS TO  
“EXTEND AVERAGE TREATMENT DURATION” TO MEET ITS GOAL OF  
\$2.9B GROSS FUNDS IN 2010.**

See Exhibit B.219 hereto attached.

**7.220 OPINION – THE “VENTURE” KNEW MARKETING TO DOCTORS  
WORKED.**

See Exhibit B.220 hereto attached.

**7.221 OPINION – THE “VENTURE” KNEW MARKETING TO PHARMACISTS WORKED.**

See Exhibit B.221 hereto attached.

**7.222 OPINION – THE “VENTURE” KNEW THAT PATIENTS AND DOCTORS WOULD CONSIDER TRIVIAL PAIN TO MERIT MODERATE TO SEVERE DESIGNATION INCLUDING INGROWN TOENAILS.**

See Exhibit B.222 hereto attached.

**7.223 OPINION – THE “VENTURE” KNEW THAT THE JICK LETTER DID NOT EVALUATE USE OF OXYCONTIN. THEY HID THIS FROM MEDICAL DOCTORS AND THE PUBLIC.**

See Exhibit B.223 hereto attached.

**7.224 OPINION – THE “VENTURE” MADE UNSUBSTANTIATED CLAIMS AND MINIMIZED ADDICTION RISK TO DOCTORS AND PATIENTS.**

See Exhibit B.224 hereto attached.

**7.225 OPINION – THE “VENTURE” MISREPRESENTED THE DEFINITION OF ADDICTION BY STATING THAT “TAKING OPIOIDS FOR PAIN RELIEF IS NOT ADDICTION”.**

See Exhibit B.225 hereto attached.

**7.226 OPINION – THE “VENTURE” PAID CHARLES O’BRIEN, WHO WROTE THE SUBSTANCE USE DISORDER PORTION OF DIAGNOSTIC AND STATISTICAL MANUAL (DSM) V. O’BRIEN SAID HE COULD “DELAY INVOICING” UNTIL THE NEXT YEAR TO AVOID DISCLOSING THESE PAYMENTS.**

See Exhibit B.226 hereto attached.

**7.227 OPINION – THE “VENTURE” RECOGNIZED THEY THERE WAS NO EVIDENCE THAT LONG TERM OPIOIDS WORKED BETTER THAN PLACEBO. THEY NEVER PERFORMED THIS STUDY.**

See Exhibit B.227 hereto attached.

**7.228 OPINION – THE “VENTURE” REPEATEDLY ACKNOWLEDGED THEIR MAFIA STATUS AND EXPLAINED HOW THEY OPERATED.**

See Exhibit B.228 hereto attached.

**7.229 OPINION – THE “VENTURE” SET UP AMERICAN PAIN FOUNDATION (APF) TO INCREASE SALES AND MISLEAD THE PUBLIC ABOUT RISKS AND BENEFITS AND A POPULATION THAT WAS 'UNTREATED'.**

See Exhibit B.229 hereto attached.

**7.230 OPINION – THE “VENTURE” SOUGHT TO EXPAND SALES INAPPROPRIATELY.**

See Exhibit B.230 hereto attached.

**7.231 OPINION – THE “VENTURE” TARGETED PHYSICIANS WHO DO NOT CONSIDER THEMSELVES PAIN EXPERTS IN ORDER TO INCREASE PRESCRIPTIONS.**

See Exhibit B.231 hereto attached.

**7.232 OPINION – THE “VENTURE” TARGETED VULNERABLE POPULATIONS.**

See Exhibit B.232 hereto attached.

**7.233 OPINION – THE “VENTURE” TOLD PHARMACIES THAT THERE WAS NO DOSE LIMIT. ADDICTION IS RELATED TO DOSE. THUS THIS MARKETING WAS AN ADDICTION CREATING MACHINE.**

See Exhibit B.233 hereto attached.

**7.234 OPINION – THE “VENTURE” TRACKED MESSAGING. THEY KNEW WHO WAS CHEATING AND PUSHING PROMOTION MESSAGE RECALL DATA (PMRD).**

See Exhibit B.234 hereto attached.

**7.235 OPINION – THE “VENTURE” TRAINED SALES REPS TO PUSH HIGH-DOSE OPIOIDS TO DOCTORS.**

See Exhibit B.235 hereto attached.

**7.236 OPINION – THE “VENTURE” USE SEX TO SELL – ENDO.**

See Exhibit B.236 hereto attached.

**7.237 OPINION – THE “VENTURE” USED AGGRESSIVE CONTROL TECHNIQUES TO INFLUENCE DOCTORS NOT EVIDENCE BASED MEDICINE.**

See Exhibit B.237 hereto attached.

**7.238 OPINION – THE “VENTURE” USED AMERICAN PAIN FOUNDATION (APF) TO HIDE THE FUNDING SOURCE FOR TALKS.**

See Exhibit B.238 hereto attached.

**7.239 OPINION – THE “VENTURE” USED AMERICAN PAIN SOCIETY (APS) AS A FRONT FOR MARKETING - "MULTI-ETHNIC STUDY = MARKETING".**

See Exhibit B.239 hereto attached.

**7.240 OPINION – THE “VENTURE” USED BRIBES TO SELL.**

See Exhibit B.240 hereto attached.

**7.241 OPINION – THE “VENTURE” USED FRONT GROUPS TO PROMOTE SALES TO WORK AROUND FDA MARKETING PROHIBITIONS.**

See Exhibit B.241 hereto attached.



**7.242 OPINION – THE “VENTURE” USED FRONT GROUPS TO SECRETLY COMMUNICATE WITH EACH OTHER. FDA AND VORSANGER OF J&J GOT THIS.**

See Exhibit B.242 hereto attached.

**7.243 OPINION – THE “VENTURE” USED PHARMACISTS TO INCREASE USE.**

See Exhibit B.243 hereto attached.

**7.244 OPINION – THE “VENTURE” USED SEX TO SELL – PURDUE.**

See Exhibit B.244 hereto attached.

**7.245 OPINION – THE “VENTURE” USED SEX TO SELL – MALLINCKRODT.**

See Exhibit B.245 hereto attached.

**7.246 OPINION – THE “VENTURE” USED SEX TO SELL.**

See Exhibit B.246 hereto attached.

**7.247 OPINION – THE “VENTURE” USED THE JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS (JCAHO) PROCESS TO INCREASE USE OF OPIOIDS.**

See Exhibit B.247 hereto attached.

**7.248 OPINION – THE “VENTURE” USED THE OPIOID POST-MARKETING REQUIREMENT CONSORTIUM (OPC) TO GENERATE FAVORABLE RESULTS, SECRETLY GHOST WRITE PAPERS ALL WITH PURPOSE OF INCREASING SALES BY MINIMIZING RISKS AND INCREASING THE POPULATION TARGETED FOR USE.**

See Exhibit B.248 hereto attached.

**7.249 OPINION – THE “VENTURE” USED UNBRANDED MESSAGING TO PROMOTE SALES TO WORK AROUND FDA MARKETING PROHIBITIONS.**

See Exhibit B.249 hereto attached.

**7.250 OPINION – THE “VENTURE” USED ‘HOOKERS, STRIPPERS AND LAP DANCERS’ AS ROUTINE SALES TECHNIQUES.**

See Exhibit B.250 hereto attached.

**7.251 OPINION – THE “VENTURE” USED “EDUCATIONAL” LISTSERV PAIN\_CHEM\_DEP TO FIND HIGH-PRESCRIBING DOCTORS TO SELL ITS OPIOIDS.**

See Exhibit B.251 hereto attached.

**7.252 OPINION – THE “VENTURE” DID NOT EMPHASIZE THE DIAGNOSES THAT ARE NOT MODERATE PAIN FOR OPIOIDS.**

See Exhibit B.252 hereto attached.

**7.253 OPINION – THE FDA ORDERED OPANA ER REMOVED FROM THE MARKET JUNE 8 2017. ENDO DID NOT ISSUE A RECALL.**

See Exhibit B.253 hereto attached.

**7.254 OPINION – THE JICK LETTER PROVIDED NO RELIABLE EVIDENCE ON THE RISK OF ADDICTION FROM OPIOID USE.**

See Exhibit B.254 hereto attached.

**7.255 OPINION – THE PURDUE MARKETING PLAN TARGETED 100,000 MEDICAL DOCTORS AND 25,000 PHARMACY AND THERAPEUTICS (P&T) MEMBERS. THERE ARE NOT 100,000 MEDICAL DOCTORS WHO HAVE EXPERIENCE TREATING CHRONIC PAIN WITH OPIOIDS. THIS EXPANDED THE USE TO MEDICAL DOCTORS WHO SHOULD NOT HAVE PRESCRIBED THE DRUG.**

See Exhibit B.255 hereto attached.

**7.256 OPINION – THE WHOLESALERS WERE A CONDUIT FOR MISINFORMATION TO PHARMACIES AND HAD THE CAPACITY TO MONITOR USE AND FAILED TO DO SO.**

See Exhibit B.256 hereto attached.

**7.257 OPINION – TITRATION IS THE KEY FOR A ‘BIGGER BONUS’ FOR THE “VENTURE” EVEN IF IT MEANS ‘ESCALATING DOSAGE AND NUMBER OF TABLETS’.**

See Exhibit B.257 hereto attached.

**7.258 OPINION – TO INCREASE SALES, THE “VENTURE” USED PRESCRIBER DATA FROM IMS TO TARGET TO HIGH-PRESCRIBING PHYSICIANS INSTEAD OF TRACKING PATTERNS OF ABUSE.**

See Exhibit B.258 hereto attached.

**7.259 OPINION – THE DEA DIDN'T BUY WAG'S ELECTRONIC RECORD ARGUMENT AND THREATENED WALGREENS WITH VIOLATIONS FOR EACH INSTANCE.**

See Exhibit B.259 hereto attached.

**7.260 OPINION – WALGREENS AND PURDUE SHARED DATA.**

See Exhibit B.260 hereto attached.

**7.261 OPINION – WALGREENS ANTICIPATED JUPITER SHUT DOWN AND DEVELOPED A WORK AROUND TO CIRCUMVENT DOJ AGREEMENT.**

See Exhibit B.261 hereto attached.

**7.262 OPINION – WALGREENS GOOD FAITH WAS DONE IN RESPONSE TO DEA ACTION.**

See Exhibit B.262 hereto attached.

**7.263 OPINION – WALGREENS KEPT SUBOXONE OFF OF FORMULARIES.**

See Exhibit B.263 hereto attached.

**7.264 OPINION – WALGREENS PHARMACIES SOLD OUTRAGEOUS AMOUNTS OF OPIOIDS II.**

See Exhibit B.264 hereto attached.

**7.265 OPINION – WALGREENS SOLD OUTRAGEOUS AMOUNTS OF OXY TO CERTAIN STORES.**

See Exhibit B.265 hereto attached.

**7.266 OPINION – WALGREENS USED A FRONT AMERICAN ACADEMY OF PAIN MEDICINE (AAPM) TO MAKE IT APPEAR THAT ITS GOOD FAITH DISPENSING (GFD) PROGRAM WAS GOOD. THE FRONT MADE CHANGES TO UNDERMINE THE EFFICACY OF THE SYSTEM.**

See Exhibit B.266 hereto attached.

**7.267 OPINION – WALGREENS USED A FRONT TO MAKE IT APPEAR THAT ITS GOOD FAITH DISPENSING (GFD) PROGRAM WAS GOOD.**

See Exhibit B.267 hereto attached.

**7.268 OPINION – WHEN MADE AWARE OF PILL MILLS PURDUE DEVELOPED A PR STRATEGY TO DEFEND ITS PRODUCT RATHER THAN A PUBLIC HEALTH STRATEGY TO PROTECT PATIENTS.**

See Exhibit B.268 hereto attached.

**7.269 OPINION – WHEN MADE AWARE OF PILL MILLS, PURDUE DEVELOPED STRATEGY TO UNDERMINE REGULATORY EFFORTS TO DEAL WITH THE PROBLEM.**

See Exhibit B.269 hereto attached.

**7.270 OPINION – WHOLESALERS WORKED IN CONCERT WITH MANUFACTURERS TO PROMOTE OPIOID USE.**

See Exhibit B.270 hereto attached.

**7.271 OPINION –THE “VENTURE” INFLUENCED THE NIH HANDBOOK ON CANCER PAIN TREATMENT AND USED IT TO INCREASE SALES.**

See Exhibit B.271 hereto attached.

**7.272 OPINION –THE “VENTURE” USED FRONT GROUPS TO ENHANCE SALES BY UNDERMINING ADDICTION RISK AND EXPANDING USE AND INFLUENCING REGULATORS. THE “VENTURE” USED THE FRONT GROUPS TO MARKET DIRECTLY TO CONSUMERS.**

See Exhibit B.272 hereto attached.

**7.273 OPINION – AMERICAN PAIN SOCIETY (APS), AMERICAN PAIN FOUNDATION (APF) AND OTHER PAIN SOCIETIES WERE FRONTS FOR THE “VENTURE”. “UNCONDITIONAL GRANTS” WERE CONDITIONED ON THE CONDITION THAT THE PAIN SOCIETIES DID THE “VENTURE’S” BIDDING.**

See Exhibit B.273 hereto attached.

**7.274 OPINION – THE “VENTURE” EXPANDED THE MARKET BY PROMOTING INAPPROPRIATE USE (LOW BACK SPASM) OF 3 YEARS DURATION WITH “SOME PAIN”.**

See Exhibit B.274 hereto attached.

**7.275 OPINION – THE “VENTURE” PUSHED LONG ACTING NARCOTICS FOR INITIAL DRUG PRESCRIPTION FOR ANY CAUSE OF PAIN INCREASING ADDICTION**

See Exhibit B.275 hereto attached.

**7.276 OPINIONS - THE “VENTURE” PUSHED Q12 RATHER THAN INCREASING DOSE FREQUENCY INCREASING ADDICTION.**

See Exhibit B.276 hereto attached.

**7.277 OPINIONS: THE SACKLER FAMILY ORIGINATED DIRECT-TO-CONSUMER DRUG MARKETING. THIS PRACTICE HAS SINCE BEEN WIDELY ADOPTED BY THE PHARMACEUTICAL AND MEDICAL DEVICE INDUSTRY.**

See Exhibit B.277 hereto attached.

**7.278 THERE WAS PURDUE SPOILIATION.**

See Exhibit B.278 hereto attached.

**7.279 OPINION – WALGREENS AND JUPITER MISCONDUCT – CORRECT MONITORING AND ACTIVELY CHANGING ORDERS TO AVOID REPORTING.**

See Exhibit B.279 hereto attached.

**7.280 OPINION – PURDUE KNEW REBATES DROVE SALES.**

See Exhibit B.280 hereto attached.

**7.281 OPINION – THE “VENTURE” HAD MANY SALES CODE VIOLATIONS – ENDO EXAMPLE**

See Exhibit B.281 hereto attached.

**7.282 OPINION – PURDUE HAD A REBATE PROGRAM WITH PRIME THERAPEUTICS.**

See Exhibit B.282 hereto attached.

**7.283 OPINION – THE “VENTURE” RELIED UPON A PSEUDO SYNDROME CALLED PSEUDOADDICTION, WHICH WAS USED BY THE “VENTURE” TO CONVINCE DOCTORS THAT PATIENTS WITH ADDICTION SYMPTOMS WERE NOT ACTUALLY ADDICTED TO OPIOIDS BUT RATHER NEEDED TO BE TREATED WITH EVER ESCALATING DOSES. A DIAGNOSIS OF PESUDOADDICTION WORSENEED THE ADDICTION AND DELAYED OR BLOCKED TREATMENT FOR ADDICTION. THIS IS NOT EVIDENCE BASED MEDICINE.**

See Exhibit B.283 hereto attached.

**7.284 OPINION – PURDUE EDITED THE AMERICAN MEDICAL DIRECTORS ASSOCIATIONS GUIDELINE FOR CHRONIC PAIN MANAGEMENT IN THE LONG-TERM CARE SETTING.**

See Exhibit B.284 hereto attached.

**7.285 OPINION – PURDUE HAD A GROSS MISUNDERSTANDING OF HOW SCIENCE WORKS AND EPIDEMIOLOGY AND STATISTICS. THE FIRST RULE OF SCIENCE IS REPETITION OF EXPERIMENTS.**

See Exhibit B.285 hereto attached.

**7.286 OPINION – THE “VENTURE” INFLUENCED PRACTITIONERS EXPLOITING OVER PRESCRIBERS AND FAILING TO REPORT MDs WHOSE PRESCRIBING LED TO DIVERSION**

See Exhibit B.286 hereto attached.

**7.287 OPINION – PURDUE MANIPULATED SUSPICIOUS ORDER MONITORING (“SOM”) BY MANIPULATING THE QUOTA SYSTEM**

See Exhibit B.287 hereto attached.

**7.288 OPINION PURDUE MARKETING PAIN TREATMENT TO ELEMENTARY SCHOOL CHILDREN**

See Exhibit B.288 hereto attached.

**7.289 OPINION PURDUE PRESENTED DATA TO THEIR SALES REPS IN THE OXYCONTIN LAUNCH MEETING THAT THE FDA SAID WOULD BE MISLEADING.**

See Exhibit B.289 hereto attached.

**7.290 OPINION – IN 2013, STEPHEN SEID, PURDUE’S VP OF NATIONAL ACCOUNTS BROUGHT PRESSURE ON WALGREENS ABOUT GOOD FAITH DISPENSING (GFD).**

See Exhibit B.290 hereto attached.

**7.291 OPINION – PURDUE REBATES TO WALGREENS BEGAN NO LATER THAN 1998.**

See Exhibit B.291 hereto attached.

**7.292 OPINION – PURDUE REMOVED DETAILED AND THOROUGH FROM REVIEW OF ABUSE DATA.**

See Exhibit B.292 hereto attached.

**7.293 OPINION – PURDUE SOLD AN UNSAFE OPIOID FOR ABOUT A YEAR BUT DID NOT ISSUE A RECALL.**

See Exhibit B.293 hereto attached.



**7.294 OPINION – PURDUE MARKETING TO DENTISTS - THIS IS OFF LABEL.**

See **Exhibit B.294** hereto attached.

**7.295 OPINION – PURDUE TRAINED WALGREENS PERSONNEL IN NARCOTICS**

See **Exhibit B.295** hereto attached.

**7.296 OPINION – PURDUE TRIED TO INFLUENCE OHIO REGULATORY AGENCIES.**

See **Exhibit B.296** hereto attached.

**7.297 OPINION – PURDUE WANTED TO RETAIN THE POWER TO SLOW THE PUBLIC HEALTH RESPONSE TO THE OPIOID CRISIS.**

See **Exhibit B.297** hereto attached.

**7.298 OPINION – REBATES DRIVE SALES OF HIGHER DOSE OPIOIDS.**

See **Exhibit B.298** hereto attached.

**7.299 OPINION – WHOLESALER PERFORMANCE AGREEMENT BETWEEN PURDUE AND CARDINAL WAS A CONCERTED ACTION TO SELL AND PROMOTE OPIOIDS.**

See **Exhibit B.299** hereto attached.

**7.300 OPINION – ‘CHRONIC NON-MALIGNANT PAIN’ CAN BE A FUNCTION OF PHYSICAL WORK AND THUS SOCIOECONOMIC STATUS. THAT PAIN IS EITHER “NORMAL” OR SHOULD BE TREATED WITH CHANGES IN WORK. THE OVERWHELMING MAJORITY OF INDIVIDUALS, INCLUDING BUT NOT LIMITED TO, TEACHERS, RETAIL WORKERS, WAITRESSES, BARBERS, JANITORS, GARBAGE COLLECTORS, AND ATHLETES, DEVELOP CHRONIC NON-MALIGNANT PAIN.**

See **Exhibit B.300** hereto attached.

**7.301 OPINION – NATIONAL INITIATIVE ON PAIN CONTROL (NIPC) (ENDO) ALLOWED OFF LABEL MARKETING**

See **Exhibit B.301** hereto attached.

**7.302 OPINION – THE “VENTURE” HAD A COMPREHENSIVE PROGRAM TO PUSH OPIOIDS INCLUDING PUSHING DIRECT-TO-CONSUMER (DTC) AND TO INEXPERIENCED PRESCRIBERS**

See **Exhibit B.302** hereto attached.

**7.303 OPINION – “VENTURE” KEY OPINION LEADERS (KOLs) SEED THE LITERATURE WITHOUT DISCLOSING INDUSTRY FUNDING**

See **Exhibit B.303** hereto attached.

**7.304 OPINION – OXYCODONE IS UP TO 3 TIMES MORE POTENT THAN PREVIOUSLY ACKNOWLEDGED BY THE “VENTURE”**

See **Exhibit B.304** hereto attached.

**7.305 OPINION – THE “VENTURE” CHANGED DIAGNOSTIC AND STATISTICAL MANUAL (DSM) ADDICTION CRITERIA**

See **Exhibit B.305** hereto attached.

**7.306 OPINION – PURDUE COULD HAVE STOPPED THIS BY TRACKING  
IMS DATA LIKE THEY DID WITH ME. DENTAL USE SHOULD HAVE  
TRIGGERED AN INTERVENTION**

See Exhibit B.306 hereto attached.

**7.307 OPINION – PURDUE TARGETED OHIO**

See Exhibit B.307 hereto attached.

**7.308 OPINION – PURDUE TOLD ITS PERSONNEL NOT TO REPORT  
GENERAL ASSERTIONS OF DIVERSION**

See Exhibit B.308 hereto attached.

**7.309 OPINION – SUMMIT COUNTY RELIED ON EXPRESSMEDS AND  
EXPRESS SCRIPTS FOR ITS FORMULARY**

See Exhibit B.309 hereto attached.

**7.310 OPINION – TEVA OFF LABEL MARKETING ACTIQ**

See Exhibit B.310 hereto attached.

**7.311 OPINION – THE 5TH VITAL SIGN WAS OPPOSED BY MEMBERS  
OF JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE  
ORGANIZATIONS (JACHO). IT INCREASED ADDICTION RATES**

See Exhibit B.311 hereto attached.

**7.312 OPINION – THE “VENTURE” CHANGED THE STANDARD OF  
CARE FOR PAIN TREATMENT WITHOUT EVIDENCE THAT THE  
CHANGE WOULD IMPROVE CARE BUT WITH EVIDENCE THAT THE  
CHANGE WOULD INCREASE PROFITS AND USE OF OPIOIDS**

See Exhibit B.312 hereto attached.

**7.313 OPINION – THE “VENTURE” CREATES A MYTHICAL PROBLEM CALLED “UNDERTREATED PAIN” AND USED THAT MYTH TO FLOOD THE US MARKET WITH THE “OPIOIDS” SOLUTION.**

See Exhibit B.313 hereto attached.

**7.314 OPINION – THE “VENTURE” KNEW PUSHING OPIOIDS WORKED**

See Exhibit B.314 hereto attached.

**7.315 OPINION – THE “VENTURE” KNEW THE JICK LETTER DID NOT ADDRESS RISK OF ADDICTION FOR OPIOID TREATMENT OF CHRONIC NON-MALIGNANT PAIN (CNMP) BUT REFUSED TO FUND A MORE COMPREHENSIVE STUDY**

See Exhibit B.315 hereto attached.

**7.316 OPINION – THE “VENTURE” MEMBERS HELPED PROMOTE USE OF OPIOIDS.**

See Exhibit B.316 hereto attached.

**7.317 OPINION – THE “VENTURE” USED MIDDLE MEN AKA “PROFESSIONAL SOCIETIES” TO HIDE PAYMENTS TO SPEAKERS**

See Exhibit B.317 hereto attached.

**7.318 OPINION – THE “VENTURE” GENERATED MEDICAL LITERATURE TO ENHANCE SALES**

See Exhibit B.318 hereto attached.

**7.319 OPINION – THE RISK OF ADDICTION FROM LONG ACTING OPIOIDS (LAOs) IS UNKNOWN. TELLING PRESCRIBER THE RISK IS LOW OR RARE IS AN ANTI-WARNING THAT IS NOT BASED ON SCIENTIFIC EVIDENCE.**

See Exhibit B.319 hereto attached.

**7.320 OPINION – THE “VENTURE” ACTED TOGETHER TO PASS LEGISLATIVE BILL S. 483, WHICH HINDERS THE DEA’S ABILITY TO INTERVENE IN SUSPICIOUS SHIPMENTS OF OPIOIDS.**

See Exhibit B.320 hereto attached.

**7.321 OPINION – THE “VENTURE” – MCKESSON’S SUSPICIOUS ORDER MONITORING (SOM) WAS INADEQUATE.**

See Exhibit B.321 hereto attached.

**7.322 OPINION – WALGREENS GOT AROUND SUSPICIOUS ORDER ISSUES - OTHER WHOLESALERS STEPPED IN.**

See Exhibit B.322 hereto attached.

**7.323 OPINIONS – PURDUE RESPONSE TO MONITORING WAS INADEQUATE.**

See Exhibit B.323 hereto attached.

**7.324 OPINION – AMERISOURCE BERGEN (“ABC”) WAS LIGHT ON ORDER MONITORING. THE ABC FOCUS IS ONLY ON RAPID GROWTH, NOT STEADY SALES. FOCUS ON BIG ACCOUNTS ONLY FOR SUSPICIOUS ORDER MONITORING.**

See Exhibit B.324 hereto attached.

**7.325 OPINION – MANUFACTURERS AND WHOLESALERS COORDINATED ACTIVITIES.**

See Exhibit B.325 hereto attached.

**7.326 OPINION – PURDUE SPENT LESS THAN 2 MINUTES REVIEWING SUSPICIOUS ORDERS.**

See Exhibit B.326 hereto attached.

**7.327 OPINION –WALGREENS CIRCUMVENTED ITS OWN POLICY TO AVOID ITS OBLIGATION TO INVESTIGATE AND REPORT SUSPICIOUS ORDERS.**

See Exhibit B.327 hereto attached.

**7.328 OPINION – THE “VENTURE” IGNORED WARNINGS OF EXCESS DRUG SALES.**

See Exhibit B.328 hereto attached.

**7.329 OPINION – “VENTURE” MEMBERS HAD AGREEMENTS WITH AUTHORIZED DISTRIBUTORS WHEREBY THEY RECEIVED DATA THAT COULD HAVE BEEN USED TO MONITOR SUSPICIOUS ORDERS. THIS DATA GAVE “VENTURE” MEMBERS VISIBILITY INTO THEIR CUSTOMER’S CUSTOMERS.**

See Exhibit B.329 hereto attached.

**7.330 OPINION – THE “VENTURE” HAD DATA THAT COULD BE USED DO SUSPICIOUS ORDER MONITORING (SOM) BUT THEY DID NOT USE IT.**

See Exhibit B.330 hereto attached.

**7.331 OPINION – WALGREENS HAD TO WORK HARD TO CIRCUMVENT CARDINAL RED FLAGGED STORES.**

See Exhibit B.331 hereto attached.

**7.332 OPINION – WALGREENS SOFTWARE WAS AN EASY WORK AROUND CONTROLS.**

See Exhibit B.332 hereto attached.

**7.333 OPINION – WALGREENS UNDERMINED ITS OWN SUSPICIOUS ORDER MONITORING (SOM) POLICY.**

See Exhibit B.333 hereto attached.

**7.334 OPINION – WALGREENS USED MONITORING TO INCREASE RATHER THAN REDUCE ABUSE.**

See **Exhibit B.334** hereto attached.

**7.335 OPINION – WALGREENS REFUSED TO LET MANUFACTURERS AND WHOLESALERS AUDIT SUSPICIOUS ORDER MONITORING (SOM).**

See **Exhibit B.335** hereto attached.

**7.336 OPINION – MANUFACTURERS AND WHOLESALERS WERE CONNECTED AT THE HIP.**

See **Exhibit B.336** hereto attached.

**7.337 OPINION – THE “VENTURE” ACTED IN CONCERT TO TARGET INAPPROPRIATE PRESCRIBERS THAT IS PRESCRIBERS WHO ARE NOT "KNOWLEDGEABLE IN THE USE OF POTENT OPIOIDS FOR THE MANAGEMENT OF CHRONIC PAIN.”**

See **Exhibit B.337** hereto attached.

**7.338 OPINION – THE “VENTURE” AIMED TO EXPAND THE INDICATIONS OF OPIOID ANALGESICS TO TREAT NON-CANCER PAIN SPECIFICALLY FOR TREATMENT OF CHRONIC PAIN AND IN PEDIATRIC POPULATIONS.**

See **Exhibit B.338** hereto attached.

**7.339 OPINION – THE “VENTURE” COOKED THE BOOKS.**

See **Exhibit B.339** hereto attached.

**7.340 OPINION – THE “VENTURE” KNEW THE 12 HOUR CLAIM WAS BOGUS.**

See **Exhibit B.340** hereto attached.

**7.341 OPINION – THE “VENTURE” LEVERAGED THE AMERICAN ACADEMY OF PAIN MEDICINE (AAPM) AND AMERICAN PAIN SOCIETY (APS) TO ADVERTISE NON-CANCER USE OF MS CONTIN TO DOCTORS, APPROVED BY THE FDA.**

See Exhibit B.341 hereto attached.

**7.342 OPINION – THE “VENTURE” MARKETING DIRECTLY TO PHARMACIES.**

See Exhibit B.342 hereto attached.

**7.343 OPINION – PURDUE MARKETING TO PHYSICIANS WHO WERE NOT “KNOWLEDGEABLE IN THE USE OF POTENT OPIOIDS FOR THE MANAGEMENT OF CHRONIC PAIN.” FROM LABEL:**

See Exhibit B.343 hereto attached.

**7.344 OPINION – THE “VENTURE” ORGANIZED LOBBYING.**

See Exhibit B.344 hereto attached.

**7.345 OPINION – THE “VENTURE” OVER PROMOTED NARCOTICS.**

See Exhibit B.345 hereto attached.

**7.346 OPINION – THE “VENTURE” PUSHED HIGHER DOSES THUS INCREASING ADDICTION.**

See Exhibit B.346 hereto attached.

**7.347 OPINION – THE “VENTURE” PUSHED NARCOTICS FOR PATIENT WHO SHOULD NOT GET THEM I.E. PATIENTS WITH DISEASES THAT ARE BETTER TREATED WITH DRUGS FOR THEIR DISEASE (OSTEOARTHRITIS) OR TO DOCTORS WHO SHOULD NOT USE THEM (FAMILY PRACTITIONERS, REHABILITATION PHYSICIANS, AND NEUROLOGISTS).**

See Exhibit B.347 hereto attached.



**7.348 OPINION – PURDUE PUSHED NO CEILING DOSE FOR OXYCONTIN INCREASING ADDICTION. THE MS CONTIN PUBLIC PERCEPTION OF END OF LIFE TREATMENT DOES NOT ACCOUNT FOR THE FACT THAT OXYCONTIN CAUSED PATIENT DEATHS.**

See Exhibit B.348 hereto attached.

**7.349 OPINION – THE “VENTURE” INFLUENCED THE FDA RISK EVALUATION AND MITIGATION STRATEGY (REMS) PROGRAM.**

See Exhibit B.349 hereto attached.

**7.350 OPINION – THE “VENTURE” SOUGHT TO INFLUENCE INTERNATIONAL ORGANIZATIONS**

See Exhibit B.350 hereto attached.

**7.351 OPINION – THE “VENTURE” SOUGHT TO USE FRONT GROUPS TO INCREASE USE.**

See Exhibit B.351 hereto attached.

**7.352 OPINION – THE “VENTURE” TRAINED SALES REPRESENTATIVES TO ABUSE THE TRUST OF DOCTORS TO SELL DRUGS.**

See Exhibit B.352 hereto attached.

**7.353 OPINION – THE “VENTURE” USED DOSING TO ADDICT PATIENTS.**

See Exhibit B.353 hereto attached.

**7.354 OPINION – THE “VENTURE” USED FORMULARY ACCESS TO INCREASE USE.**

See Exhibit B.354 hereto attached.

**7.355 OPINION – THE “VENTURE” USED J&J LAWYER ANGAROLA TO INCREASE OPIOID USE**

See Exhibit B.355 hereto attached.

**7.356 OPINION – THE “VENTURE” INFLUENCED THE MANAGED CARE MARKET TO INCREASE SALES - RELATIONSHIP BETWEEN THE MANUFACTURERS AND PHYSICIANS, PATIENTS, AND PHARMACISTS.**

See Exhibit B.356 hereto attached.

**7.357 OPINION – THE “VENTURE” SOUGHT TO ADDICT VENERABLE POPULATIONS. REPS WERE PAID TWICE THE BONUS DOLLARS FOR LANDING A NURSING HOME, HOME HEALTH AND HEALTH AID VS A HOSPITAL OR PAIN CENTER.**

See Exhibit B.357 hereto attached.

**7.358 OPINION – THE “VENTURE’S” EFFORTS TO KEEP KEY INFORMATION ON THE HARMFUL EFFECTS OF THEIR PRODUCTS A SECRET, THEIR ILLEGAL ACTS SECRET HAS MADE THE ADDICTION, ABUSE, AND OVERDOSE PROBLEM WORSE.**

See Exhibit B.358 hereto attached.

**7.359 OPINION – THE “VENTURE” MARKETING TO INAPPROPRIATE PRESCRIBERS.**

See Exhibit B.359 hereto attached.

**7.360 OPINION – THE “VENTURE” USED A VARIETY OF SALES TECHNIQUES TO CONVINCE PHYSICIANS TO PRESCRIBE AND PATIENTS TO USE OPIOIDS TO TREAT NON-MALIGNANT PAIN (NMP)**

See Exhibit B.360 hereto attached.

**7.361 OPINION – THE NY-ATTORNEY GENERAL’S OFFICE  
DEMANDED THAT THE “VENTURE” REMOVE A MISLEADING CLAIM  
THAT “MOST DOCTORS” SUGGEST PATIENTS USUALLY DO NOT  
BECOME ADDICTED TO EXTENDED RELEASE OPIOIDS**

See Exhibit B.361 hereto attached.

**7.362 OPINION – OPIOIDS INCREASE SENSITIVITY TO PAIN IN SOME  
PATIENTS**

See Exhibit B.362 hereto attached.

**7.363 OPINION – THE OPIOID PMR CONSORTIUM (OPC)  
COMPOSITION**

See Exhibit B.363 hereto attached.

**7.364 OPINIONS: THE SACKLER FAMILY ORIGINATED  
GHOSTWRITING AND THE USE OF MEDICAL JOURNALS AS MEDICAL  
MARKETING TOOLS TO INCREASE DRUG SALES. THIS PRACTICE HAS  
SINCE BEEN WIDELY ADOPTED BY THE PHARMACEUTICAL AND  
MEDICAL DEVICE INDUSTRY.**

See Exhibit B.364 hereto attached.

**7.365 OPINION – THE VISUAL ANALOGUE SCALE IS NOT RELIABLE;  
THEREFORE, ALL PAIN STUDIES THAT USE IT ARE  
UNINTERPRETABLE.**

See Exhibit B.365 hereto attached.

**7.366 OPINION – THERE ARE CULTURAL AND ETHNICAL  
DISPARITIES IN THE WAY INDIVIDUALS PERCEIVE AND EXPERIENCE  
PAIN.**

See Exhibit B.366 hereto attached.

**7.367 OPINION – ADDICTION DEFINITION**

See **Exhibit B.367** hereto attached.

**7.368 OPINION – AMERICAN PAIN SOCIETY (APS), AMERICAN PAIN FOUNDATION (APF) AND OTHER PAIN SOCIETIES WERE FRONTS FOR THE “VENTURE”. “UNCONDITIONAL GRANTS” WERE CONDITIONAL ON THE CONDITION THAT THE PAIN SOCIETIES DID THE “VENTURE’S” BIDDING.**

See **Exhibit B.368** hereto attached.

**7.369 OPINION – THE “VENTURE” ACTED IN CONCERT TO STRATEGICALLY UTILIZE THIRD PARTIES, INCLUDING BUT NOT LIMITED, TO FRONT GROUPS, KEY OPINION LEADERS, ADVOCACY GROUPS, UNBRANDED PROMOTION, PROFESSIONAL SOCIETIES, TRADE GROUPS AND COMPANY-SPONSORED NON-DRUG SPECIFIC PROMOTION, AND CONTINUING EDUCATION PROGRAMS, TO CREATE THE CONDITIONS NECESSARY TO CARRY OUT THE GOALS OF THE “VENTURE”, OBSCURING THE “VENTURE’S” ROLE.**

See **Exhibit B.369** hereto attached.

**7.370 OPINION – WA SOUGHT TO AND DID CIRCUMVENT CARDINAL RED FLAG STORE SHIPMENTS.**

See **Exhibit B.370** hereto attached.

**7.371 OPINION – WALGREENS AND PURDUE HAD A REBATE PROGRAM THAT RELATED TO FORMULARY ACCESS AMONG OTHER THINGS.**

See **Exhibit B.371** hereto attached.

**7.372 OPINION – WALGREENS AUDITING WAS INADEQUATE.**

See **Exhibit B.372** hereto attached.

**7.373 OPINION – WALGREENS CREATED COMMUNICATIONS FOR  
PURDUE FOR DISTRIBUTION TO CUSTOMERS AND PHARMACISTS.**

See Exhibit B.373 hereto attached.

**7.374 OPINION –WALGREENS SUSPICIOUS ORDER MONITORING WAS  
INADEQUATE.**

See Exhibit B.374 hereto attached.

**7.375 OPINION – WALGREENS WAS A WHOLESALER TO ITSELF**

See Exhibit B.375 hereto attached.

**7.376 OPINION – WALGREENS SYSTEMS COULD BE MANIPULATED TO  
ALLOW STORES TO CIRCUMVENT QUANTITY RESTRICTIONS - KNOWN  
ISSUE - 'THIS IS HOW THE SYSTEM ALWAYS WORKED'**

See Exhibit B.376 hereto attached.

**7.377 OPINION – WHEN WALGREENS CIRCUMVENTED CARDINAL  
RED FLAGS THEY BOUGHT A LARGE STAKE IN  
AMERISOURCEBERGEN.**

See Exhibit B.377 hereto attached.

**7.378 OPINION – WHOLESALERS PROMOTED DRUG USE.**

See Exhibit B.378 hereto attached.

**7.379 OPINION – YALE FORMULARY IS VERY IMPORTANT.**

See Exhibit B.379 hereto attached.

**7.380 OPINION – PURDUE TRAINED WALGREENS PHARMACISTS IN  
1996**

See Exhibit B.380 hereto attached.

**7.381 OPINION – “VENTURE” MEMBER JANSSEN MISREPRESENTED THE ADDICTION POTENTIAL OF OPIOIDS IN GENERAL AND ITS OPIOIDS IN PARTICULAR.**

See Exhibit B.381 hereto attached.

**7.382 OPINION – THE “VENTURE” WORKED TOGETHER TO CREATE GHOST WRITTEN INDUSTRY EDITED PAPERS TO SUPPORT THEIR MARKETING.**

See Exhibit B.382 hereto attached.

**7.383 OPINION: AS REQUESTED BY THE FDA, THE “VENTURE”, WORKING AS THE “INDUSTRY WORKING GROUP,” CREATED A DOCUMENT TO DEFINE “ABUSE”, “ADDICTION” AND “OPIOID PSEUDO-ADDICTION” AND AID THE FDA IN THE CREATION OF THE RISK EVALUATION AND MITIGATION STRATEGY (REMS). THUS THE FDA PLACED THE CONVICTED CRIMINAL AND FDA RULE BREAKERS IN CHARGE OF THE CHICKENS.**

See Exhibit B.383 hereto attached.

**7.384 OPINION – THE “VENTURE” HAS FALSELY STATED THAT PATIENTS WILL NOT BECOME ADDICTED IF PATIENTS ARE TAKING OPIOIDS FOR LEGITIMATE, “MEDICAL PURPOSES.”**

See Exhibit B.384 hereto attached.

**7.385 OPINION – ACTAVIS HAD MARKETING AGREEMENTS WITH SOME DISTRIBUTORS AND PROVIDED MCKESSON WITH “TALKING POINTS” TO SELL OXYMORPHONE TO PHARMACISTS.**

See Exhibit B.385 hereto attached.

**7.386 OPINION – THE “VENTURE” DID NOT INCLUDE FDA-MANDATED DRUG LABEL WARNINGS IN THE PHYSICIAN’S DESK REFERENCE (PDR) FOR ALL OF THEIR DRUGS THEY SOLD FOR EVERY YEAR THAT THEY WERE SOLD. THE “VENTURE” MEMBERS HAD A DUTY TO ENSURE THAT DOCTORS RECEIVED THESE WARNINGS. WITHOUT INCLUSION IN THE PDR, MANY DOCTORS DID NOT RECEIVE THE FDA-MANDATED WARNING LABELS.**

See Exhibit B.386 hereto attached.

**7.387 OPINION: PLANNING COMMITTEE MEMBERS, TEACHERS/PRESENTERS, AND AUTHORS OF CME SHOULD DISCLOSE RELATIONSHIPS WITH COMMERCIAL INTERESTS.**

See Exhibit B.387 hereto attached.

**7.388 OPINION – PURDUE USED THE 2001 LABEL CHANGE TO EXPAND THE TARGET MARKET. ALL SIMILAR OPIOID LABELS CHANGED AT THE SAME TIME.**

See Exhibit B.388 hereto attached.

**7.389 OPINION – OPIOIDS HAVE PARADOXICAL EFFECTS ON PAIN INCREASING PAIN IN SOME PATIENTS. IT CAN BE DIFFICULT (PERHAPS IMPOSSIBLE IN A STUDY) TO DISTINGUISH TOLERANCE AND HYPERALGESIA, AND IT IMPOSSIBLE TO DO SO SOLELY BASED ON THE CLINICAL OBSERVATION OF THE PATIENT. THIS IS NOT ACCOUNTED FOR IN ANY PAIN OPIOID STUDIES. AS A RESULT THE VALIDITY OF ALL THESE STUDIES IS QUESTIONABLE. THIS IS ANOTHER REASON THAT ENRICHED ENROLMENT WITH RANDOMISED WITHDRAWAL (EERW) STUDY DESIGN IS INVALID AND THAT THE FDA VIEW THAT “WE KNOW [OPIOIDS] WORK” IS NONSENSE**

See Exhibit B.389 hereto attached.

**7.390 OPINION: THE “VENTURE” MARKETING GENERIC DRUGS, SPECIFICALLY TARGETING HIGH PRESCRIBING PHYSICIANS TO “INCREASE THEIR SCRIPTS.” THIS INCLUDES PHYSICIANS WHO ARE OVERLY AND INAPPROPRIATELY PRESCRIBING DRUGS.**

See Exhibit B.390 hereto attached.

**7.391 OPINION: THE FDA NEVER APPROVED OXYCONTIN AS A TREATMENT FOR CHRONIC PAIN.**

See Exhibit B.391 hereto attached.

**7.392 OPINION: THE FDA ONLY APPROVED OXYCONTIN FOR USE BY TREATERS WHO WERE “KNOWLEDGEABLE IN THE USE OF POTENT OPIOIDS FOR THE MANAGEMENT OF CHRONIC PAIN.”**

See Exhibit B.392 hereto attached.

**7.393 OPINION – DR. ROBERT RAPPAPORT WAS CAPTURED BY INDUSTRY AND COORDINATED WITH THE “VENTURE” TO INCREASE OPIOID USE, EASE OPIOID APPROVALS, EXPAND OPIOID INDICATIONS AND MINIMIZE ADDICTION RISK.**

See Exhibit B.393 hereto attached.

**7.394 OPINION – THIS IS AN OVERVIEW OF THE US DISTRIBUTION AND REIMBURSEMENT SYSTEM FOR OUTPATIENT DRUGS**

See Exhibit B.394 hereto attached.

**7.395 OPINION –WALGREENS SYSTEMS COULD BE MANIPULATED TO ALLOW STORES TO CIRCUMVENT QUANTITY RESTRICTIONS. THIS WAS A KNOWN ISSUE. “[T]HIS IS HOW THE SYSTEM ALWAYS WORKED”**

See Exhibit B.395 hereto attached.



**7.396 OPINION – “VENTURE” KEY OPINION LEADERS (KOLs)  
CREATED POORLY SUPPORTED MEDICAL LITERATURE TO SUPPORT  
CLAIMS THAT WOULD EXPAND THE MARKET FOR OPIOIDS.**

See Exhibit B.396 hereto attached.

**7.397 OPINION – AROUND 1997, “VENTURE” MEMBERS ORTHO-  
MCNEIL (JOHNSON & JOHNSON) AND PURDUE BEGAN CO-  
PROMOTING ULTRAM SR, INTENDED FOR THE USE OF MORE  
MODERATE PAIN.**

See Exhibit B.397 hereto attached.

**7.398 OPINION – CEPHALON’S ACTIQ WAS NOT INDICATED FOR, BUT  
WAS MARKETED OFF LABEL FOR MINOR PAIN.**

See Exhibit B.398 hereto attached.

**7.399 OPINION – THE “VENTURE” AGREE NOT TO COMPETE ON  
SAFETY.**

See Exhibit B.399 hereto attached.

**7.400 OPINION – DEA CITED WALGREENS FOR BAD PRACTICES AT  
PERRYSBURG DISTRIBUTION CENTER.**

See Exhibit B.400 hereto attached.

**7.401 OPINION – DICTIONARY OF TERMS FROM WHOLESALER  
AGREEMENTS.**

See Exhibit B.401 hereto attached.

**7.402 OPINION – WHOLESALER CONNECTIONS TO PHARMACIES.**

See Exhibit B.402 hereto attached.

**7.403 POSSIBLE LIMITATIONS TO MY ANALYSIS.**

See Exhibit B.403 hereto attached.

**7.404 OPINION – THE “VENTURE” ACTED IN CONCERT TO:**

See Exhibit B.404 hereto attached.

**7.405 OPINION – THE “VENTURE” RECOGNIZED THAT THERE WAS NO EVIDENCE THAT OPIOIDS WERE INDICATED FOR THE TREATMENT OF CHRONIC NON-MALIGNANT PAIN.**

See Exhibit B.405 hereto attached.

**7.406 OPINION – WHOLESALE DISTRIBUTORS ALSO OWN AND OPERATE SPECIALTY PHARMACIES.**

See Exhibit B.406 hereto attached.

**7.407 OPINION – PRESCRIPTION OPIOIDS CAUSED THE OPIOID CRISIS.**

See Exhibit B.407 hereto attached.

**7.408 OPINION – DOCTORS ON THE “VENTURE’S” PAYROLL ADMITTED THAT PSEUDOADDICTION DESCRIBES BEHAVIORS ‘CLEARLY CHARACTERIZED AS DRUG ABUSE’ AND PUT THE “VENTURE” AT RISK OF ‘SANCTIONING ABUSE.’**

See Exhibit B.408 hereto attached.

**7.409 OPINION – PURDUE CLAIMED OXYCONTIN CR WAS APPROVED FOR POST-OPERATIVE PAIN. THIS IS NOT TRUE.**

See Exhibit B.409 hereto attached.

**7.410 OPINION – PURDUE DID NOT REMOVE THE 160 MG DOSE FORM THE LABEL UNTIL 2011 ALTHOUGH IT WAS AWARE OF THE FACT THAT ITS RISKS OUTWEIGHED BENEFITS BY 2001.**

See Exhibit B.410 hereto attached.

**7.411 OPINION – PURDUE EDITED THE AMERICAN MEDICAL DIRECTORS ASSOCIATIONS GUIDELINE FOR CHRONIC PAIN MANAGEMENT IN THE LONG-TERM CARE SETTING.**

See Exhibit B.411 hereto attached.

**7.412 OPINION – PURDUE STOPPED SELLING THE 160 MG PILL BECAUSE IT WAS NOT SAFE AND EFFICACIOUS BUT NEVER DID A RECALL.**

See Exhibit B.412 hereto attached.

**7.413 OPINION – THE “VENTURE” - ROXANE (NOW MALLINCKRODT) INCLUDING DISTRIBUTORS MARKETING UNAPPROVED DRUGS.**

See Exhibit B.413 hereto attached.

**7.414 OPINION – OUT THE DRUGS TARGETED FOR GOOD FAITH DISPENSING (GFD), ONLY THE USE RATES OF OXYCONTIN WERE AFFECTED.**

See Exhibit B.414 hereto attached.

**7.415 OPINION – THE “VENTURE” CONTINUALLY REMINDED ITS STAFF THAT SHIFTS TO LOWER DOSES WOULD RESULT IN HUGE MONETARY LOSSES FOR THE “VENTURE”.**

See Exhibit B.415 hereto attached.

**7.416 OPINION – THE “VENTURE” USED A VARIETY OF SALES TECHNIQUES TO CONVINCE PHYSICIANS TO PRESCRIBE AND PATIENTS TO USE OPIOIDS TO TREAT CHRONIC NON-MALIGNANT PAIN.**

See Exhibit B.416 hereto attached.

**7.417 OPINION – THE “VENTURE” SEEDED THE LITERATURE TO INCREASE USE OF OPIOIDS IN MINORITY POPULATIONS.**

See **Exhibit B.417** hereto attached.

**7.418 OPINION – THE “VENTURE” SHARED INFORMATION.**

See **Exhibit B.418** hereto attached.

**7.419 OPINION – THE “VENTURE” SHOULD HAVE TRAINED DOCTORS TO TELL PATIENTS WHAT TO DO WITH EXTRA PILLS AND HOW TO PROPERLY DISPOSE OF THEM. THIS SHOULD BE IN THE PACKAGE INSERT.**

See **Exhibit B.419** hereto attached.

**7.420 OPINION – THE “VENTURE” USED SEX TO SELL PRODUCT – INSYS.**

See **Exhibit B.420** hereto attached.

**7.421 OPINION – THE VISUAL ANALOGUE SCALE IS NOT RELIABLE AND THEREFORE ALL PAIN STUDIES THAT USE IT ARE UNINTERPRETABLE.**

See **Exhibit B.421** hereto attached.

**7.422 OPINION – VIP = VOLUME INCENTIVE PROGRAM (PRICING SELL MORE GET INCREASED IN REBATE). THIS IS AN EXAMPLE OF THE “VENTURE” IN OPERATION. OXY DRIVES SALES MALLINCKRODT AND WALGREENS.**

See **Exhibit B.422** hereto attached.

**7.423 OPINION – WALGREENS AGREED TO CREATE “COMMUNICATIONS” ON HYSINGLA.**

See **Exhibit B.423** hereto attached.

**7.424 OPINION – WALGREENS AND MALLINCKRODT WORKED TOGETHER ON SUSPICIOUS ORDER MONITORING (SOM) FAILURE IS JOINT RESPONSIBILITY.**

See Exhibit B.424 hereto attached.

**7.425 OPINION – WHOLESALERS CONTROLLED ENTIRE CHAINS OR PHARMACY OPIOID USE AND HAD A SWITCH PROGRAM.**

See Exhibit B.425 hereto attached.

**7.426 OPINION – ALLERGAN DEFINED “CLOSED FORMULARY” AND “INCENTIVE FORMULARY” AS FOLLOWS:**

See Exhibit B.426 hereto attached.

**7.427 OPINION – ENDO WAS EITHER TOO CHEAP TO ADD ITS OPIOID LABELS TO THE 2014 PDR OR COMPLETELY IRRESPONSIBLE FOR THIS FAILURE TO WARN LEARNED INTERMEDIARIES OF ANY DATA CONCERNING THESE DANGEROUS DRUGS.**

See Exhibit B.427 hereto attached.

**7.428 OPINION – “VENTURE” FUNDED PAPER AND CME ARE BIASED TO INCREASE OPIOID USE.**

See Exhibit B.428 hereto attached.

**7.429 OPINION – MARKETING HAS A RETURN ON INVESTMENT (ROI) AND INFLUENCES DOCTORS.**

See Exhibit B.429 hereto attached.

**7.430 OPINION – MCKESSON HAD MARKETING AGREEMENTS WITH MALLINCKRODT, PURDUE AND TEVA.**

See Exhibit B.430 hereto attached.

**7.431 OPINION – WHOLESALERS WORKED IN CONCERT WITH MANUFACTURERS TO PROMOTE OPIOID USE THROUGH PHARMACIES.**

See **Exhibit B.431** hereto attached.

**7.432 OPINION – LABEL CHANGES ON ABUSE POTENTIAL CHANGES OVER TIME**

See **Exhibit B.432** hereto attached.

**7.433 OPINION – THE “VENTURE” MISLED PRESCRIBERS ABOUT THE POTENCY OF OXYCONTIN. THE “VENTURE” TARGETED NON-CANCER PATIENTS TO INCREASE MARKET SIZE TO INAPPROPRIATE PATIENTS. THE “VENTURE” TARGETED NON-CANCER PATIENTS TO MISLEAD PRESCRIBERS ABOUT THE POTENCY AND THUS ADDICTION POTENTIAL OF OXYCONTIN.**

See **Exhibit B.433** hereto attached.

**7.434 OPINION – PURDUE RECOMMENDED USING OXYCONTIN FOR SHINGLES. THIS IS AN EFFORT TO INCREASE PROFITS BY ENCOURAGING USE IN DISEASE IT WAS NOT INDICATED FOR.**

See **Exhibit B.434** hereto attached.

**7.435 OPINION – PURDUE WAS AWARE OF THE FACT THAT DOCTORS WERE NOT AWARE OF THE POTENCY OF OXYCONTIN. INSTEAD OF CORRECTING THIS MISIMPRESSION, PURDUE CAPITALIZED ON IT TO INCREASE OXYCONTIN USE.**

See **Exhibit B.435** hereto attached.

**7.436 OPINION – THE “VENTURE” INFLUENCED WHO GUIDELINES AND THEN USED THEM TO UP SELL.**

See **Exhibit B.436** hereto attached.

**7.437 OPINION – THE CLINICAL STUDIES CITED IN OPIOID DRUG LABELS CHANGED OVER TIME.**

See **Exhibit B.437** hereto attached.

**7.438 OPINION: THE “VENTURE” USED THE AMERICAN PAIN FOUNDATION AND INDUSTRY FUNDED KEY OPINION LEADERS (KOLs) TO CREATE LITERATURE FOR THE PURPOSE OF INFLUENCING POLICY MAKERS AND REPORTERS AND FAILED TO DISCLOSE ALL OF THE INDUSTRY CONNECTIONS OF THE KOLs.**

See **Exhibit B.438** hereto attached.

**7.439 OPINION – THE PAIN CARE FORUM (PCF) WAS MADE UP OF THE FOLLOWING MEMBERS AND WAS HELD AT THE OFFICE OF POWERS, PYLES, SUTTER & VERVILLE A WASHINGTON DC ATTORNEY’S OFFICE.**

See **Exhibit B.439** hereto attached.

**7.440 OPINION – THIRD PARTY ENDORSEMENTS ARE MORE EFFECTIVE AT INFLUENCING BEHAVIOR THAN FIRST PARTY ENDORSEMENTS. IN ADDITION, THESE THIRD-PARTY ENDORSEMENTS TARGETED CONSUMERS AND CIRCUMVENTED LEARNED INTERMEDIARY PHYSICIANS. THE COMPANIES DID NOT INCLUDE APPROPRIATE WARNINGS AND CAUTIONS IN THEIR ENDORSEMENTS TO CONSUMERS.**

See **Exhibit B.440** hereto attached.

**7.441 OPINION – “VENTURE” MEMBERS PURDUE AND JANSSEN WORKED TOGETHER TO INCREASE OPIOID USE.**

See **Exhibit B.441** hereto attached.

**7.442 OPINION – THE “VENTURE” MEMBERS SHARED KEY OPINION LEADERS (KOLs) PORTENOY, CARR.**

See **Exhibit B.442** hereto attached.

**7.443 OPINION – ROBERT WOOD JOHNSON FOUNDATION (RWJF) ASSISTED THE “VENTURE”.**

See **Exhibit B.443** hereto attached.

**7.444 OPINION – ALLERGAN DID MANY BAD THINGS, SUCH AS LYING ABOUT ADDICTION, EXPANDING THE OPIOID MARKET, CLAIMED PAIN WAS A DISEASE, AND ENTERED INTO SETTLEMENTS AND GUILTY PLEAS.**

See **Exhibit B.444** hereto attached.

**7.445 OPINION – MALLINCKRODT KNEW THEY WERE FEEDING ADDICTS. THEY THOUGHT THIS WAS FUNNY. I DISAGREE.**

See **Exhibit B.445** hereto attached.

**7.446 OPINION – THE “VENTURE” USED FORMULARIES TO EXPAND THE OPIOID MARKET.**

See **Exhibit B.446** hereto attached.

**7.447 OPINION: THE “VENTURE” ENGAGED IN CONCERTED ACTION TO INCREASE SALES BY MINIMIZING ADDICTION RISK, ENCOURAGING OVERUSE, ENCOURAGING USE BY PHYSICIANS WHO THE BLACK BOX WARNING SAID SHOULD NOT USE OPIOIDS.**

See **Exhibit B.447** hereto attached.

**7.448 OPINION – THE INDICATIONS FOR THE “VENTURE’S” OPIOID MEDICATIONS CHANGED OVER TIME.**

See **Exhibit B.448** hereto attached.

**7.449 OPINION – THE DOSAGE FORMS AND STRENGTHS LISTED ON THE “VENTURE’S” OPIOID MEDICATION LABELS CHANGED OVER TIME.**

See **Exhibit B.449** hereto attached.



**7.450 OPINION – THE BLACK BOX WARNINGS FOR THE  
“VENTURE’S” OPIOID MEDICATIONS CHANGED OVER TIME.**

See Exhibit B.450 hereto attached.

**7.451 OPINION: THE “VENTURE” CREATED AND SUPPORTS THE  
USE OF THE ENRICHED ENROLLMENT RANDOMIZED WITHDRAWAL  
(EERW) STUDY DESIGN FOR APPROVING ANALGESICS FOR  
CHRONIC NON-CANCER PAIN. AS OF 2016, 5 DRUGS HAVE BEEN  
APPROVED FOR CHRONIC PAIN ON THE BASIS OF EERW STUDIES.  
EERW IS FLAWED METHODOLOGY.**

See Exhibit B.451 hereto attached.

**7.452 OPINION – PURDUE WAS AWARE OF THE FACT THAT  
PATIENTS WERE ILLEGALLY OBTAINING OPIOIDS UNDER MY NAME.  
IT FAILED TO REPORT THIS. THIS METHOD COULD HAVE BEEN  
USED TO TRACK DIVERSION IN GENERAL.**

See Exhibit B.452 hereto attached.

**7.453 OPINION – OHIO MEDICAID DEPENDED ON THE PHARMACY  
BENEFIT MANAGERS (PBMS) FOR FORMULARY DRUG SELECTION.**

See Exhibit B.453 hereto attached.

**7.454 OPINION – TEVA USED ITS HOTLINE TO OFF LABEL  
MARKET.**

See Exhibit B.454 hereto attached.

**7.455 OPINION – ALL THESE OPIOIDS HAD THE SAME RISK OF  
ADDICTION FOR THE SAME EFFECTIVE DOSE AND THE WARNINGS  
SHOULD HAVE AT A MINIMUM BEEN THE STRONGEST THAT WAS  
APPROVED FOR ANY OF THEM.**

See Exhibit B.455 hereto attached.

**7.456 OPINION: THE FDA NEVER APPROVED OXYCONTIN AS A TREATMENT FOR CHRONIC PAIN.**

See **Exhibit B.456** hereto attached.

**7.457 OPINION – THE CLINICAL STUDIES ON THE “VENTURE’S” OPIOID DRUG LABELS CHANGED OVER TIME.**

See **Exhibit B.457** hereto attached.

**7.458 OPINION – THE “VENTURE” MEMBERS USED VARIOUS METHODS TO PUSH DRUGS - FORMULARY ACCESS WAS KEY.**

See **Exhibit B.458** hereto attached.

**7.459 OPINION – WALGREENS CIRCUMVENTED THE DEA SETTLEMENT.**

See **Exhibit B.459** hereto attached.

**7.460 OPINION – PURDUE RESISTED IMPROVEMENTS IN SUSPICIOUS ORDER MONITORING.**

See **Exhibit B.460** hereto attached.

**7.461 OPINION – WALGREEN’S SOM WAS A JOKE.**

See **Exhibit B.461** hereto attached.

**7.462 OPINION – THIS IS THE TIMELINE OF FDA ACTIVITY THAT FDA CREATED OF ITS ACTIVITY RELATED TO OPIOID ADDICTION – IT OMITTS REGULATORY CAPTURE.**

See **Exhibit B.462** hereto attached.

**7.463 OPINION – THE “VENTURE” GHOST WROTE THE REVIEW OF ENRICHED ENROLLMENT RANDOMIZED WITHDRAWAL (EERW) STUDIES. THIS IS UNETHICAL AND ALTERED THE PAPER IN A MATERIAL WAY TO MAKE IT APPEAR THAT EERW STUDIES ARE LEGITIMATE WHEN THEY ARE NOT.**

See Exhibit B.463 hereto attached.

**7.464 OPINION – THE “VENTURE” USED DISCOUNT CARDS TO INCREASE SALES**

See Exhibit B.464 hereto attached.

**7.465 OPINION – PURDUE HAD AN EXTENSIVE MARKETING PROGRAM FOR HOSPITAL FORMULARY ACCESS.**

See Exhibit B.465 hereto attached.

**7.466 OPINION – PURDUE SPOILIATED DOCUMENTS AND HARD DRIVES.**

See Exhibit B.466 hereto attached.

**7.467 OPINION – THIS IS A PLACED AD THAT APPEARS TO BE A MEDICAL ARTICLE THAT WAS GHOST WRITTEN FOR A KEY OPINION LEADER (KOL) WHO DID NOT DISCLOSE HIS CONFLICTS.**

See Exhibit B.467 hereto attached.

**7.468 OPINION – MCKESSON BLAMES MANUFACTURERS AND AVOIDS ITS OWN RESPONSIBILITY.**

See Exhibit B.468 hereto attached.

**7.469 OPINION – THIS DESCRIBES PHARMACEUTICAL PRICING AND PHARMACY BENEFIT MANAGER (PBM) AND MANUFACTURING MANIPULATION OF THE SYSTEM TO INFLUENCE DRUG USE.**

See Exhibit B.469 hereto attached.

**7.470 OPINION – THIS IS PURDUE’S AND THE INDUSTRY’S  
PRODUCT DISTRIBUTION METHODOLOGY.**

See Exhibit B.470 hereto attached.

**7.471 OPINION – THE POST MARKETING STUDIES WERE DONE BY  
THE “VENTURE” AS A WHOLE. THIS IS AN EXAMPLE OF REGULATORY  
CAPTURE. NO RATIONAL REGULATORY AGENCY WOULD INVITE  
CONVICTED CRIMINALS TO CONDUCT STUDIES ON THEIR OWN  
PRODUCTS. INDUSTRY HELPED CREATE OR ACTUALLY PERFORM THE  
FISHBAIN STUDY.**

See Exhibit B.471 hereto attached.

**7.472 OPINION – J&J MARKETING NARCOTICS TO INAPPROPRIATE  
PATIENTS.**

See Exhibit B.472 hereto attached.

**7.473 OPINION – DEFINITION – INSTEAD OF NAMING PARTICULAR  
COMPANIES IN MY OPINIONS, I REFER TO MANUFACTURING AND  
DISTRIBUTOR DEFENDANTS (INCLUDING THEIR ASSOCIATED  
INDIVIDUALS AND/OR ORGANIZATIONS) AS THE “VENTURE”.**

See Exhibit B.473 hereto attached.

**7.474 OPINION – THE BOARDS OF J&J AND RWJF OVERLAP. IT IS  
IMPROPER FOR A NON-PROFIT TO DO SOMETHING THAT BENEFITS  
A BOARD MEMBER’S COMPANY.**

See Exhibit B.474 hereto attached.

**7.475 OPINION – THE “VENTURE” USED AND CONTROLLED MANY FRONT GROUPS TO UNDERMINE ADDICTION RISK AND INCREASE MARKET TO INAPPROPRIATE PATIENTS**

See Exhibit B.475 hereto attached.

**7.476 OPINION – MALINCKRODT OPINIONS**

See Exhibit B.476 hereto attached.

**7.477 OPINION – “VENTURE” MEMBERS HAD AGREEMENTS WITH WHOLESALERS, INCLUDING BUT NOT LIMITED TO: "**

See Exhibit B.474 hereto attached.

**7.478 OPINION – “VENTURE” MEMBERS HAD INVENTORY LICENSE AGREEMENTS WITH WALGREENS WHEREBY THEY RECEIVED DATA THAT COULD HAVE BEEN USED TO MONITOR SUSPICIOUS ORDERS. THIS DATA GAVE VENTURE MEMBERS VISIBILITY INTO THEIR CUSTOMER’S CUSTOMERS.**

See Exhibit B.478 hereto attached.

**7.479 OPINION – CVS’S SUSPICIOUS ORDER MONITORING SYSTEM DID NOT MONITOR SUSPICIOUS ORDERS. IT’S SOM POLICY SPECIFIED THAT IF MULTIPLE ORDERS FOR THE SAME STORE ARE FLAGGED DURING THE SAME MONTH, ALL ORDERS AFTER THE FIRST ORDER WILL NOT BE INVESTIGATED AND WILL BE AUTOMATICALLY RELEASED BASED ON THE RELEASE OF THE FIRST ORDER**

See Exhibit B.479 hereto attached.

**7.480 OPINION – WALMART HELPED ACTAVIS MARKET OPIOIDS**

See Exhibit B.480 hereto attached.

**7.481 OPINION – THE GAO DOCUMENTED BAD CONDUCT BY  
PURDUE THAT INCREASED ADDICTION**

See Exhibit B.481 hereto attached.

**7.482 OPINION – CARDINAL DELIVERED MANUFACTURERS  
MARKETING MESSAGES TO CVS**

See Exhibit B.482 hereto attached.

**7.483 OPINION – OPIOIDS ARE NEVER MENTIONED AS AN OPTION  
FOR RX OF RHEUMATOID ARTHRITIS.**

See Exhibit B.483 hereto attached.

**7.484 OPINION – OPIOIDS ARE NOT RECOMMENDED FOR RX OF  
OSTEOARTHRITIS**

See Exhibit B.484 hereto attached.

**7.485 OPINION – OPIOIDS SHOULD NOT BE USED FOR LOW BACK  
PAIN. CHRONIC OPIOIDS ARE VERBOTEN.**

See Exhibit B.485 hereto attached.

**7.486 OPINION – OPIOIDS ARE NOT TREATMENT FOR  
FIBROMYALGIA**

See Exhibit B.486 hereto attached.

**7.487 OPINION – RITE AID PROVIDED MARKETING SERVICES TO  
TEVA**

See Exhibit B.487 hereto attached.

**7.488 OPINION – THESE ARE THE MEMBERS OF THE “VENTURE”**

See Exhibit B.488 hereto attached.

**7.489          OPINION – MEMBERS OF THE “VENTURE” ENTERED  
AGREEMENTS WITH THE DEA AND DOJ FOR VIOLATING THE LAW**

See **Exhibit B.489** hereto attached.

## 8 LIMITATIONS

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Limitations to my analysis include:

- 1) I could not review missing or destroyed documents
- 2) I could not review documents withheld as non-responsive
- 3) I could not review documents withheld as privileged
- 4) I could not review redacted language
- 5) I did not review correspondence in non-produced personal emails
- 6) I did not review correspondence in non-produced text messages
- 7) Multiple productions remain incomplete
- 8) I do not have access to all of the documents produced in other state specific litigation.
- 9) Monitoring reports under Corporate Integrity Agreements were not produced
- 10) Ethics Hotline reports under Corporate Integrity Agreements were not produced

See **Exhibit B.403** hereto attached.



## 9 FACTS AND DATA REVIEWED, READ OR CONSIDERED

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Production is ongoing, and I reserve the right to supplement this list as more documents become available.

I have reviewed, read or considered:

- 1) The published medical literature<sup>60</sup> on Opioids, Pain, Addiction, Pain Treatments, NSAIDs. See **Exhibit C**.
- 2) Documents and metadata produced by the Defendants, Plaintiffs, and Third Parties specifically referenced in **Exhibit D** hereto attached.
- 3) Legal complaints filed against opioid manufacturers and distributors in Massachusetts and Florida.
- 4) The Master Amended Complaint filed in this case (Opiate MDL).
- 5) Deposition transcripts (with exhibits) taken in this case (Opiate MDL).
- 6) Other historical deposition transcripts (including Covington and Fishbain) taken in prior Purdue litigation.
- 7) Articles published in magazines and newspapers referenced in Opinions.
- 8) Websites (including government sites) referenced in Opinions.
- 9) News media publications referenced in Opinions.
- 10) 1984-2017 Editions of the Physician's Desk Reference.

It is my expectation that I will review the Expert Reports of Plaintiffs' and Defendants' Experts once they are made available.

It is my understanding that production is ongoing. Should documents be produced, I reserve the right to supplement my opinions.

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<sup>60</sup> Every attempt was made to include literature cited in this report and to the extent a piece of literature was missed, it is incorporated herein.

## 10 PRIOR EXPERT TESTIMONY

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- **2015**
  - *Anderson et al v. Aldrich Chemical Company et al.*, Docket No. 2009CV003457 (Wi Cir. Ct.)
  - *Smead v. Chr. Hansen Inc. et al.*, Docket No. 2009CV003112 (Wis Cir. Ct.)
  - *Boyd v. Ameron International Corporation, et al.*, Docket No. RG14738647 (Cal.Super.)
  - *Norful vs Cooper Bussmann*, Docket No. 1222-CC00961 (Mo. Cir. Ct.)
  - *Solorzano v. Honeywell*, Docket No. GD-15-008069 (PA Ct. Comm. Pleas)
  - *Emerson v. Union Pacific*, Docket No. RG-13698637 (Cal.Super.)
  - *Trejo v. Hyster et al.*, Docket No. BC574146 (Cal.Super.)
  - *Aoki v. DePuy, et al.*, Docket No. 3-13-cv-1071-K, MDL No. 2244 (U.S.D.C. N.D. TX)
- **2016**
  - *Amesquita et al v. Gilster-Mary Lee, et al.*, Docket No. ED 99266 (MO Ct. App., E. Dist.)
  - *Jo Levitt vs. Merck*, Docket No. 06-CV-00818-W-DW (U.S.D.C. W.D. MO)
  - *Crawford v. Gold Coast*, Docket No. 13-EV-017885-B (Fulton County, GA)
  - *Tyler vs. American Optical, et al.*, Docket No. LA CV16-02337 JAK (ASx) (U.S.D.C. C.D. CA)
  - *Ortwein vs. CertainTeed*, Docket No. RG13701633 (Cal.Super.)
  - *Olson vs. Metalclad*, Docket No. A102605 (Cal. App.)
- **2017**
  - *Wurster v. The Plastics Group, Inc.*, Docket No. 4-14-cv-503-CRW-SBJ (U.S.D.C. S.D. Iowa)
  - *Zampa v. v. Georgia-Pacific LLC, et al.*, Docket No. RG16836998 (Cal.Super.)
  - *Williams v. UCC*, Docket No. 16-CI-1842 (Ky. Cir. Ct.)
  - *Darapel v. Cargill Flavors*, Docket No. 12-CI-446 (Ky. Cir. Ct.)
- **2018**
  - *Leavitt v. Johnson and Johnson, et al.*, Docket No. RG1782401 (Cal.Super.)
  - *Ingham v. Johnson & Johnson, et al.*, Docket No. 4:17-CV-1857 SNLJ (U.S.D.C. E.D. MO)
  - *Cynthia Hayes, as Executrix of the Estate of Donna Ann Hayes v. J& J*, Docket No. 16-CI-03503 (Ky. Cir. Ct.)
  - *In re NCAA*, Docket No. 05-17-00951-CV, 543 S.W.3d 487 (Tex. Ct. App.)
  - *Thompson v. Air & Liquid Systems Corp., et al.*, Docket No. 18-2-05736-7 (Wash.Super.)
- **2019**
  - *Fong v. Johnson and Johnson, et al.*, Docket No. 2:18-CV-00470 (U.S.D.C. C.D. CA)

## **11 COMPENSATION**

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My billing rate in this litigation is \$650 per hour for depositions and \$600 per hour for trial testimony and preparation.

## 12SIGNATURE

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### RESERVATION OF RIGHTS

This report is a statement of opinions I expect to express in this matter and the basis and reasons for those opinions. This report summarizes only my current opinions and analyses to date, which are subject to change depending upon ongoing discovery and additional information. I respectfully reserve the right to supplement my report in light of this and any other additional fact discovery, opinions by other experts, and/or trial testimony. I also respectfully reserve the right to provide rebuttal opinions and testimony in response to other experts, and rebuttal testimony in response to any fact witnesses. In connection with my anticipated trial testimony in this action, I may use as exhibits various documents produced in this litigation that refer to or relate to the matters discussed in this report. In addition, i respectfully reserve the right to use animations, demonstratives, enlargements of actual attachments, and other information in order to convey my opinions.

I understand that i may be asked to provide further opinions and analyses on other issues, including in response to analyses provided by other experts. I will do so at the appropriate time set by the court.

Executed on this 25th day of March, 2019, in Attelboro, MA.



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Report of David S. Egilman, MD, MPH

March 25, 2019 in Opiate MDL Litigation (MDL 2804)

Exhibit B.66, David S. Egilman Report Opiate Litigation

## OPINION – “VENTURE” DISTRIBUTOR ABC WORKED WITH MANUFACTURES TO MARKET OPIOIDS.

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PPLP004397461

ABCDMDL00320068

ABCDMDL00320057

PPLPC022000986875

INSYS-MDL-008053958

### SERVICES AGREEMENT

This **SERVICES AGREEMENT** (the “Agreement”) is made and entered into as of September 30, 2016, (“Effective Date”) by and between **PURDUE PHARMA L.P.** (“Company” or “Purdue”) with principal offices at One Stamford Forum, Stamford, Connecticut 06901-3431 and **AMERISOURCEBERGEN SERVICES CORPORATION** (“Vendor”) with an address of - 1300 Morris Drive, Chesterbrook, Pennsylvania 19087.

1. Defined Terms.

“Company Materials” means those materials to be provided by Company for distribution to Vendor under this Agreement.

2. Services. Vendor is engaged by Company to educate pharmacies about Butrans® (buprenorphine) Transdermal System using ABC's CustomConnect Email Campaign services to reach and message pharmacy customers targeting products as determined by Purdue. The email campaign Services will include:

- A one-time customizable Email blast to target customer
  - Pricing includes up to 5,000 targets
  - The estimated number of targets for this specific campaign is 2,000
  - Additional fees may apply for additional targets
- Target deployment is no later than December 31, 2016

Company shall approve any product-related materials, prior to distribution under this Agreement, and shall retain all intellectual property rights in the Company Materials distributed hereunder. No product-related materials may be distributed without Company's approval.

Exhibit B.85, David S. Egilman Report Opiate Litigation

## OPINION: McKESSON AND PURDUE CO-MARKETED PURDUE DRUGS

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PPLPC004000245298\_ Seid discussing best ways to position Oxycontin reformulation through McKesson Connect

I'm not asking for your ok on the program cost. We have already discussed it. This is the program we decided to go with rather than the fax blast programs. I gets prime exposure for one week and then goes on the web site permanently. I was asking for your ok with the ad that they will be using that will drive the customer to the order page with the reformulated Oxycontin® and will include the FAQ sheet that we sent them. The cost is \$4500 compared to \$7000 for the other programs that did not get as much exposure.

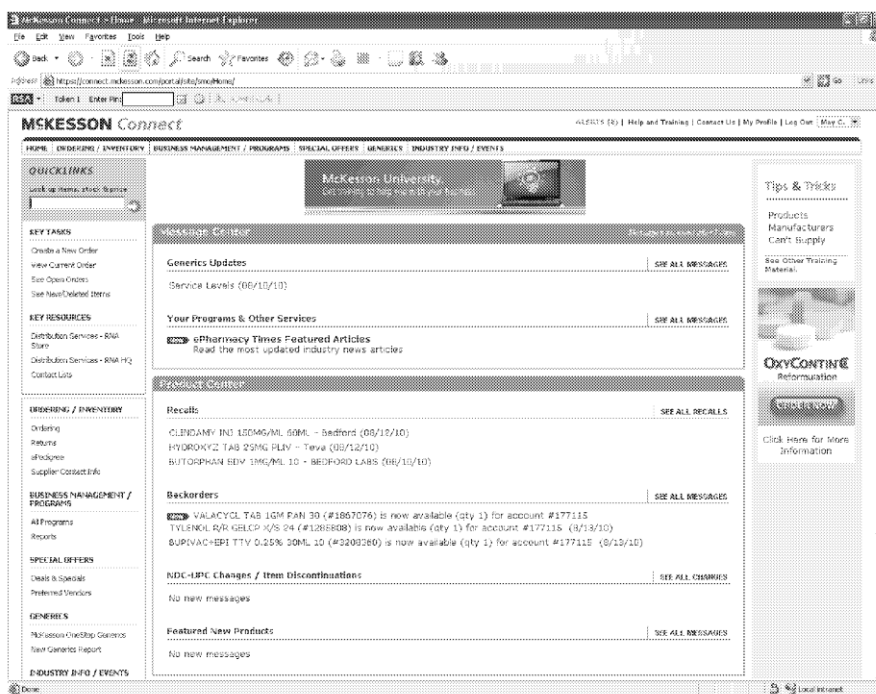
Exhibit B.86, David S. Egilman Report Opiate Litigation

## **OPINION - McKESSON PUSHED OXYCONTIN**

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HI

## Exhibit B.86, David S. Egilman Report Opiate Litigation



HIGHLY CONFIDENTIAL-SUBJECT TO MDL 2804 PROTECTIVE ORDER

MCKMDL00353308



## OPINION – THE “VENTURE” GROSSLY MISLED DISTRIBUTORS AND PATIENTS WITH THE CLAIM THAT “FEAR OF ADDICTION IS EXAGGERATED” WITHOUT OFFERING SUPPORTING EVIDENCE.

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[From 1996 OxyContin press release](#)

BASIS:

Why is pain undertreated?

The reasons why pain remains so inadequately managed are many, but several have been identified: 1) poor assessment by healthcare professionals, 2) underreporting by patients who accept pain as an inevitable consequence of disease, and 3) underuse of pain medications because of unwarranted fears of uncontrollable side effects and/or addiction by physicians and patients alike.

What is being done about this problem?

In response to these concerns, new guidelines for the treatment of acute pain and cancer pain were published in the December 20, 1995 issue of Journal of the American Medical Association (JAMA), encouraging patients to become more active in managing their personal pain.

Patients must communicate with physicians/nurses.

According to Mitchell B. Max, M.D., chairman of the American Pain Society Quality of Care Committee, which developed the new guidelines, "Patients should let their doctor or nurse know when they are in pain; if the current treatment is not working, it should be adjusted. Outpatients should be able to talk to a doctor or nurse by telephone 24 hours a day to adjust their pain medication if needed."

The fear of addiction is exaggerated.

One cause of patient resistance to appropriate pain treatment -- the fear of addiction -- is largely unfounded. According to Dr. Max, "Experts agree that most pain caused by surgery or cancer can be relieved, primarily by carefully adjusting the dose of opioid (narcotic) pain reliever to each patient's need, and that there is very little risk of addiction from the proper uses of these drugs for pain relief."

Paul D. Goldenheim, M.D., Vice President of **Purdue Pharma** L.P. in Norwalk, Connecticut, agrees with this assessment. "Proper use of medication is an essential weapon in the battle against persistent pain. But too often fear, misinformation and poor communication stand in the way of their legitimate use."

Exhibit B.100, David S. Egilman Report Opiate Litigation

## OPINION – HDMA WAS RESPONSIBLE FOR SALE OF UNAPPROVED OPIOIDS

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**From:** Ducca, Anita <aducca@hdmanet.org>  
**Sent:** Monday, April 27, 2009 7:59 PM  
**Subject:** FW: RE: Clarification of FDA's Directive Regarding Marketing of Unapproved Drugs

DATE: April 27, 2009

TO: HDMA Distributor Member Primary Contacts  
Distributor Members of the Industry Relations Counsel (IRC)  
Regulatory Affairs Committee (RAC)  
Distributor Members of the Returns Task Force (RTF)

RE: Clarification of FDA's Directive Regarding Marketing of Unapproved Drugs

This is to follow up on HDMA's request to FDA that it provide a list of those National Drug Codes (NDCs) for the products subject to the Agency's March 30, 2009 Warning Letters and April 9 follow-up letters to certain manufacturers of unapproved drug products. HDMA sought this information from FDA based on a request made by members on our most recent RAC conference call. The response from FDA, including the requested NDCs, is copied below.

In the Agency's documents, FDA had indicated that manufacturers may be subject to enforcement action if they do not stop manufacturing and distributing certain unapproved prescription drug products. It has been HDMA's assumption that these Warning Letters and subsequent communications also may extend to pharmaceutical wholesale distributors because FDA indicated in its March 31, 2009 Questions and Answers document published on its website that "distributors have 90 days after the dates of the Warning Letters to cease further shipment of existing products." FDA Questions and Answers Concerning Unapproved Narcotics; see also FDA Adopts Interim Plan to Avoid Shortage of Medically Necessary Opioid; FDA Announces Extension of Enforcement Discretion.

Please also note that the e-mail from FDA below further states that "*These products should not be in commerce after the grace period expires.*"

In working through these issues, HDMA emphasizes that each company should work diligently with its own counsel and trading partners to determine how it will implement this directive from FDA.

HDMA will include this topic on its next Regulatory Affairs Committee Conference call to discuss whether further follow-up or other clarification from FDA is necessary.

Please feel free to contact me with any questions you may have.

*Anita*

Anita T. Ducca  
Senior Director, Regulatory Affairs  
Healthcare Distribution Management Association (HDMA)  
901 North Glebe Rd., Suite 1000  
Arlington, VA 22203  
(703) 885-0240  
Fax: (703) 812-5282

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Anda\_Opioids\_MDL\_0000067636

Exhibit B.100, David S. Egilman Report Opiate Litigation

e-mail: [aducca@hdmanet.org](mailto:aducca@hdmanet.org)  
[www.HealthcareDistribution.org](http://www.HealthcareDistribution.org)

---

**From:** Walther, Sakineh H [mailto:Sakineh.Walther@fda.hhs.gov]  
**Sent:** Friday, April 24, 2009 3:15 PM  
**To:** Ducca, Anita  
**Cc:** Levy, Michael  
**Subject:** RE: Clarification of FDA's Directive Regarding Marketing of Unapproved Drugs

Dear Ms. Anita Ducca,

Regarding your email to Dr. Throckmorton requesting the list of products and NDC numbers for the narcotic drug products subject to FDA's warning letters, below please find your requested information. Please note that these firms have 60 days to stop manufacturing and 90 days to stop distributing these products from the date of warning letters issuance of March 30, 2009. These products should not be in commerce after the grace period expires.

You can find the NDC numbers for drug products at: <http://www.fda.gov/cder/ndc/database/default.htm>

Please let me know if I can be of any further help.

Thank you.

Sakineh Wather  
CDER Office of Compliance  
301-796-3349

Firms	Products	NDC #
Boehringer Ingelheim Roxane Inc.	Roxicodone Tablet, 5 mg	14288-*911
Roxane Laboratories, Inc.	Hydromorphone Hydrochloride Tablets, 2 mg & 4 mg	00054-4394
		00054-8394
Glenmark Pharmaceuticals Inc.		
	Morphine Sulfate Tablets, 15 mg	68462-*202
Lannett Company, Inc.		
	Hydromorphone HCl Tablets, 2mg and 4mg	00527-1353
		00527-1354
Lehigh Valley Technologies Inc.		
	Morphine Sulfate Tablets, 15 mg & 30 mg	64950-203
		64950-212
Physicians Total Care, Inc.		
	Morphine Sulfate Immediate Release Tablets, 30 mg;	
	Hydromorphone Tablets, 2 mg & 4 mg	

2

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Anda\_Opioids\_MDL\_0000067637

Exhibit B.100, David S. Egilman Report Opiate Litigation

54868-4973  
54868-3165  
54868-4969

Xanodyne Pharmaceuticals Inc.  
Roxicodone Tablet, 5 mg  
66479-\*580

## Exhibit B.109, David S. Egilman Report Opiate Litigation

## Opinion – Manufacturers used wholesalers as conduit for marketing

**MEMORANDUM**

**Purdue Pharma LP**  
One Stamford Forum  
Stamford, CT 06901  
Tel (203) 588-7315  
Fax (203) 588-6216

**To:** Steve Seid

**From:** Shelton Benson

**Re:** McKesson Ca.

**Date:** June 24, 2010

Met with Yuri Kasinsky and May Chow to discuss the current plans for the transition to reformulated Oxycontin®. The following are the key discussion points and results.

- The discussion I had with May Chow were to reconfirm our previous conversations and the meeting we had at HDMA. We talked about the two programs that seemed to make the most sense, Rx Bulletin and Fax Blast. The RxBulletin is going to require two weeks lead time. The Fax Blast can be done in 48 hours. As I was talking to May, working within their perimeters we may have some problems. We decided to meet at the trade show and further discuss the programs. We decided that the Fax Blast should probably go out one to two week prior to the 1<sup>st</sup> ship date and the Rx Bulletin go out on August 17<sup>th</sup> and 19<sup>th</sup>.
- Another program that just became available last week is the E-video Detailing program that is a 4 minute video that is on McKesson Connect for one week and on the Rx Detail Home page indefinitely. It is geared towards the pharmacists and gives them the ability to ask questions at the end of the video. The cost is \$7500. I thought this would be a great vehicle for RxPatrol. I presented the new RxPatrol piece to Yuri and May. It was very well received.



PPLPC00400023993  
4\_image - 2010 merr

Exhibit B.111, David S. Egilman Report Opiate Litigation

## OPINION – MCKESSON PROVIDED THE “VENTURE” BANG FOR THE BUCK IN TERMS OF ENHANCED SALES.

*Purdue National Accounts  
& Trade Relations*

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**From:** Benson, Shelton  
**Sent:** Wednesday, August 04, 2010 11:11 AM  
**To:** Seid, Stephen  
**Subject:** RE: McKesson Connect program

I'm not asking for your ok on the program cost. We have already discussed it. This is the program we decided to go with rather than the fax blast programs. I get prime exposure for one week and then goes on the web site permanently. I was asking for your ok with the ad that they will be using that will drive the customer to the order page with the reformulated Oxycontin® and will include the FAQ sheet that we sent them. The cost is \$4500 compared to \$7000 for the other programs that did not get as much exposure.

**Shelton Benson**

**Exe. Nat'l Accts Mgr.  
Purdue Pharma LP  
Cell: 832-372-4336**

---

**From:** Seid, Stephen  
**Sent:** Wednesday, August 04, 2010 10:06 AM  
**To:** Benson, Shelton  
**Subject:** RE: McKesson Connect program

How much?

*Steve Seid  
Purdue National Accounts  
& Trade Relations*

---

**From:** Benson, Shelton  
**Sent:** Wednesday, August 04, 2010 11:04 AM  
**To:** Seid, Stephen  
**Subject:** McKesson Connect program

Just wanted to get your ok. Is it ok for me to let May know that it is ok to go ahead with the program to run 8/16 thru 22<sup>nd</sup>?

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PPLPC004000245299

Exhibit B.111, David S. Egilman Report Opiate Litigation

**To:** Benson, Shelton[Shelton.Benson@pharma.com]  
**From:** Seid, Stephen  
**Sent:** Wed 8/4/2010 9:19:10 PM  
**Subject:** RE: McKesson Connect program

Thanks

*Steve Seid*  
*Purdue National Accounts*  
*& Trade Relations*

---

**From:** Benson, Shelton  
**Sent:** Wednesday, August 04, 2010 9:10 PM  
**To:** Seid, Stephen  
**Subject:** Re: McKesson Connect program

Steve  
Let me get back to you. That information is at home. I know the fax blast went out to 2600 but were limited to 2 pages which would not work with FPI.

---

**From:** Seid, Stephen  
**To:** Benson, Shelton  
**Sent:** Wed Aug 04 20:56:44 2010  
**Subject:** RE: McKesson Connect program

And the reach is?

*Steve Seid*  
*Purdue National Accounts*  
*& Trade Relations*

---

**From:** Benson, Shelton  
**Sent:** Wednesday, August 04, 2010 8:55 PM  
**To:** Seid, Stephen  
**Subject:** Re: McKesson Connect program

Steve  
The original programs we discussed were \$6500/7000. When we met with Martha and May we decided that McKesson Connect for \$4500 had more reach and was a better bang for our buck.

---

**From:** Seid, Stephen  
**To:** Benson, Shelton  
**Sent:** Wed Aug 04 20:48:35 2010  
**Subject:** RE: McKesson Connect program

I still wanted to know the cost whether we discussed it or not. If I didn't like what they were doing and/or the cost I would pull it. As I remember we discussed \$3500

*Steve Seid*

CONFIDENTIAL

PPLPC004000245298



## Exhibit B.129, David S. Egilman Report Opiate Litigation

**OPINION – “VENTURE” MEMBER MCKESSON MARKETED OPIOIDS.****Build Visibility, Drive Results**

McKesson Manufacturer Marketing helps raise your brand's visibility among pharmacists. In hospitals and long-term care facilities, it can help your brand gain acceptance on more formularies, increase sales and mitigate share erosion to competing brand and generic medications. In the retail pharmacy segment, higher visibility helps educate pharmacists about the benefits of stocking your brand.

**Pharmacist Awareness**

Pharmacist-awareness programs give you more ways to build brand visibility and help pharmacists coach patients to achieve the best results.

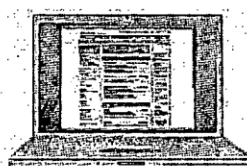
**DirectRx™ Advertising and Messaging** feature your brand's ads and screen messages on McKesson Connect, the online ordering portal used by all McKesson hospital and independent-pharmacy customers, with links to your brand site or sales materials, and to the product ordering system.

**RxBulletin™** delivers product-launch, item discontinuation and NDC number-change information to approximately 7,000 recipients at Health Mart and other independent pharmacies, plus thousands of hospital and long-term care pharmacists, via HTML e-mail messages with links to your product's Web page and the McKesson Connect ordering portal.

**RxMail™** sends your brand's printed material directly to approximately 6,000 recipients at Health Mart and other independent pharmacies. It's ideal for product launches and major announcements that require supporting information.

**Fax Blast** provides fast, flexible access to 5,000 Health Mart and other independent pharmacies for product-launch alerts, special offers, promotions and formulation or NDC changes.

**NotifyRx™** delivers real-time communications to the point of dispensing on patient-safety issues, recalls, changes in appearance or formulation, safe disposal and dosage alerts.

**Pharmacist Education**

Building pharmacists' knowledge of your brand's attributes, as well as safety and adherence issues, can encourage them to help patients achieve optimal outcomes.

**RxDetail On Demand™** delivers your brand's video presentations to retail and hospital pharmacists for anytime viewing. The McKesson Connect portal alerts pharmacists to your video, which also is archived, and lets you post an interactive survey for viewers.

**RxUpdate™** delivers clinical information from your product experts on safe dispensing, patient coaching and other clinical topics to independent retail pharmacists via direct mail and the McKesson Connect portal.



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## Exhibit B.129, David S. Egilman Report Opiate Litigation

## Maximize the Value of Retail Pharmacy

McKesson Manufacturer Marketing makes the retail pharmacy a powerful platform for influencing consumer choices at every stage of the brand life cycle. Innovative distribution solutions help put your brand on pharmacy shelves. In-store promotions target consumer awareness. Leveraging pharmacists' clinical training and patient relationships helps improve the trial-prescription experience for patients and physicians, and provides personal coaching to help improve patients' long-term medication adherence.



### Pharmacy Stocking/Distribution

These programs put your brand on pharmacy shelves, ready for dispensing to patients.

**RxFocus Autoship™** targets immediate launch shipments to retail pharmacies with high sales history in your brand's category. This enables those pharmacies to fill initial prescriptions while reducing potential returns and increasing detailing efficiency.

**Priority Express Rx™** helps new blockbuster brands build launch momentum from day one. Autoshipments to retail pharmacies within 72 hours of receipt at McKesson distribution centers enable immediate dispensing.

**Prefer Rx™** showcases your product in this program as the preferred brand in its category to more than 9,200 retail pharmacies, driving consistent reordering and helping slow erosion to competing generics and branded products.

**RxPak™** encourages pharmacies to stock frequently prescribed brands by delivering discount-priced, unit-of-use packages from McKesson's FDA-compliant repackaging facility. RxPak also produces a variety of compliance-packaging solutions.



### Patient Awareness

These solutions help distinguish your brand in retail pharmacies to build consumer awareness.

**FrontEdge Merchandiser™** delivers and installs promotional and educational materials on monthly visits to retail pharmacies, ensuring proper placement with execution tracking.

**Diabetes Life Center®**, exclusive to Health Mart pharmacies, centralizes diabetes-care products, plus educational and promotional materials, in a branded location dedicated to this valuable patient segment.

**Health Mart Circulars** reach consumers at approximately 2,700 pharmacy counters and offer a direct-to-household option, providing an effective medium for brand advertising.



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CAH\_MDL2804\_02100394

## Exhibit B.129, David S. Egilman Report Opiate Litigation

**Patient Trial — NRx** (Acquisition of New Rx)

Targeting initial prescriptions, these programs help your brand establish positive patient relationships. Pharmacists educate patients on ways to adhere to therapy and achieve positive treatment outcomes.

**TrialScript®**, the industry's leading alternative to sampling programs, gives patients an active role in therapy. The physician gives the patient a voucher with the first prescription, which the patient redeems at the pharmacy for a free trial medication. Patient data captured at the pharmacy supports downstream adherence initiatives.

**Burgopak™** is an engaging compliance-packaging solution that delivers your brand's trial medication with a co-pay discount card and adherence-promoting educational materials in an attractive, cost-effective package. Burgopak also produces custom compliance packaging for retail distribution.

**Patient Adherence — TRx** (Total Rx Long-Term Solutions)

Use these programs to build lasting patient relationships that drive adherence. Targeted pharmacist coaching and direct-to-patient communications foster patient satisfaction and help support optimal treatment outcomes.

**LoyaltyScript®**, the industry-leading adherence platform, integrates flexible point-of-dispensing co-pay subsidies with permission-based patient outreach and support to strengthen patients' relationships with your brand and motivate long-term adherence.

**eVoucherRx™**, the industry-leading electronic-coupon program, lets your brand automatically apply patient co-pays to a target co-pay you define. Co-pay offsets reduce the cost barrier to compliance, promoting patient satisfaction, increased adherence and future refills. eVoucherRx helps manufacturers to allay affordability concerns for both the physician and patient, with co-pay savings that are applied automatically as the prescription claim is processed.

**Pharmacy Intervention Program** helps increase adherence to your brand through five-minute patient-coaching interventions delivered by retail pharmacists. Interventions focus on individuals' barriers to adherence and help them devise personalized adherence plans.

**Unclaimed Prescription Program**, a behavioral-based outbound telephone solution, helps recapture prescriptions at risk of abandonment. Sponsored interventions, delivered on behalf of the pharmacy, encourage patients to reconnect with their prescriptions and help them devise plans for adhering to therapy.

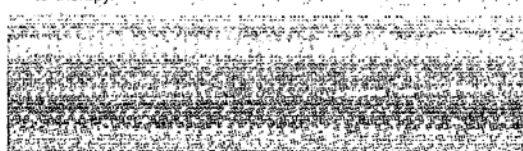
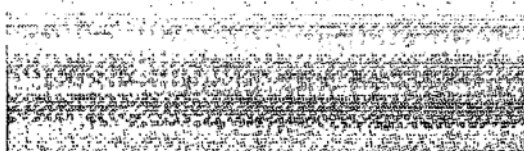


Exhibit B.135, David S. Egilman Report Opiate Litigation

## **OPINION – DISTRIBUTOR MARKETING DROVE SALES.**

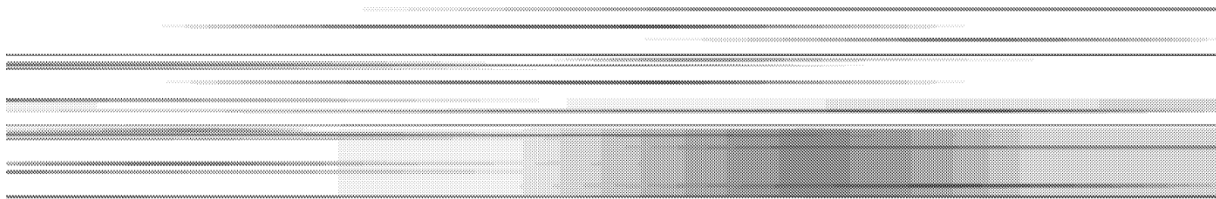
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CON

Exhibit B.135, David S. Egilman Report Opiate Litigation



## McKesson Manufacturer Marketing



Prepared For:

Cephalon, Inc. - ACTIQ<sup>®</sup> and FENTORA<sup>®</sup> Proposal  
Chris Doerr - Associate Director, Trade Operations

January 19, 2012

HIGHLY CONFIDENTIAL-SUBJECT TO MDL 2804 PROTECTIVE ORDER

MCKMDL00353374



Exhibit B.135, David S. Egilman Report Opiate Litigation

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**PROPOSAL**

**Objective:**

**Educate pharmacists regarding new REMS requirements for ACTIQ® and FENTORA®.**

McKesson offers the following Pharmacy Education Platforms which could be leveraged by Cephalon to prepare pharmacists for consumer and healthcare professional (HCP) on questions regarding the new REMS requirements for ACTIQ® and FENTORA®.

**ACTIQ® and FENTORA®**

**RxMail** – Fast, flexible access to more than 5,500 Health Mart and other independent pharmacies with direct mail delivery of Cephalon's product message. Mailers can be targeted by territory, state, or historical sales. Content provided by Cephalon. McKesson review to be no more than five (5) business days.

**Cost:**

- RxMail: \$3.25 to \$7.25 per store based on size and weight

Cephalon must provide RxMail content at least two (2) weeks prior to scheduled mail date. Performance metrics are currently under development as an enhancement to the programs.

**RxBulletin** - When you need to communicate concise information quickly, RxBulletin is the solution. This program quickly delivers your HTML e-mail message to approximately 7,000 pharmacists, with a direct link to your product's Web page or McKesson *Connect*. RxBulletin offers rapid delivery of time-sensitive messages and requires minimal development time. Content is provided by Cephalon.

***Skills and Capabilities***

- Offerings of educational awareness to pharmacists, as well as education of a clinical nature to pharmacists.

The **Rxmail** and **RxBulletin** programs detailed above could be leveraged by Cephalon to also educate pharmacists on the new REMS requirements for ACTIQ® and FENTORA® and the new restricted distribution program designed to help ensure appropriate patient selection as well as safe use of the products.

By leveraging McKesson's customer relationships, customers are more likely to read and act on your information. These programs provide you with fast and flexible means of communicating with customers. To increase the effectiveness of the communication, messaging can be targeted to customer segments based on geography or specialty.

These programs are ideal for product launch alerts, educational information, new formulation, NDC changes, and product discontinuations. Content is provided by Cephalon.

Exhibit B.135, David S. Egilman Report Opiate Litigation

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**PROPOSAL**

- Ability to scale up or scale down internal resources as needed to execute educational programs.

All McKesson offerings have turnkey implementation processes, with teams dedicated to ensuring a timely and effective program execution. Programs currently in the market are highly automated and ready to launch once the business rules have been established and all required information submitted by the customer. Program requirements, including design specifications are provided. All associated content would be provided by Cephalon.

- Ability to implement programs with short notice.

As previously mentioned, all McKesson offerings have turnkey implementation processes, with teams dedicated to ensuring a timely and effective program execution. Programs currently in the market are highly automated and ready to launch once the business rules have been established and all required information submitted by the customer.

Program requirements, including design specifications are provided. All associated content would be provided by Cephalon.

**Recommendation:**

The focus of our **program design** is to deliver educational materials to pharmacists through existing pharmacy workflow avenues.

The program as designed will leverage McKesson's unprecedented connectivity in the marketplace and build on any of your existing pharmacy and patient support efforts. While our experience serves as a guide to our recommendations, we are aware each product has unique challenges.

Created from a growing portfolio of proven and innovative program options from multiple McKesson business units, McKesson offers strategic solutions to deliver the resources and expertise to help your brand:

- Educate pharmacists on brand attributes and clinical issues to elevate their role in patient care
- Enhance pharmacists' brand awareness through multiple communication platforms, online ordering, and in-store promotions
- Measure ROI at the tactical and program levels, and provide metrics that surface and support continuing refinements

Delivering an unmatched combination of communication, promotion, distribution options, plus targeted analytics of exclusive data, McKesson will enable Cephalon to set strategies that prioritize opportunities, optimize resources, and maximize profitability.

McKesson partners with pharmaceutical manufacturers such as Cephalon to define and execute customized strategies targeting key awareness, sales, and distribution goals at all stages of the product life cycle.

McKesson's multiple awareness programs ensure pharmacists have access to the most current product information and give Cephalon more ways to build brand visibility by showing pharmacists when to recommend Cephalon products and how to counsel patients on achieving the best results.

By educating and providing pharmacists opportunities to increase their knowledge of Cephalon products' benefits, safety and adherence issues, they can feel confident recommending and answering questions about these products to patients and HCP.

## Exhibit B.135, David S. Egilman Report Opiate Litigation

**PROPOSAL****Timeline:**

- Week of January 30th - RxBulletin
- Week of February 6th - RxMail
- Week of February 27th - RxBulletin
- Week of March 26<sup>th</sup> - RxBulletin

*\*Timelines can be changed if necessary based on Cephalon's needs*

*To address these educational objectives, we are recommending the following:*

<b>RxMail.....</b>	<b>\$3.25 - \$7.25 (based on weight and size)</b>
Fast, flexible access to more than 5,500 Health Mart and other independent pharmacies direct mail delivery of Cephalon's product message. Content provided by Cephalon. McKesson review to be no more than five (5) business days.	
<b>RxBulletin.....</b>	<b>\$4,000 per e-mail message</b>
Quickly delivers HTML e-mail message to 7,000 pharmacy recipients, with a direct link to your product Web site or McKesson <i>Connect</i> . Content provided by Cephalon. McKesson review to be no more than five (5) business days.	
Cephalon must provide content at least two weeks prior to scheduled date of e-mail distribution. Performance metrics provided by McKesson.	

## Exhibit B.135, David S. Egilman Report Opiate Litigation

**McKesson Manufacturer Marketing Contract****Product Promotional Agreement**

McKesson agrees to distribute three (3) e-mail messages promoting the products identified below to 7,000 retail pharmacy recipients.

McKesson also agrees to distribute four hundred sixty three (463) mailers to our top Independent Pharmacies selling ACTIQ<sup>®</sup> and FENTORA<sup>®</sup>.

**\*Discount applied to programs**

<b>SERVICES</b>	<b>FEES</b>
RxBulletin (3 e-mails)	\$10,800 (*10% discount)
RxMail	\$2,778 (\$5 -6/ltr estimate)
<b>Total Fee:</b>	<b>\$13,578</b>

McKesson shall invoice Cephalon, Inc. ("Cephalon") for the amount of \$13,578 for these services and Cephalon shall pay such amount upon receipt of invoice.

Promotional Product: ACTIQ<sup>®</sup> and FENTORA<sup>®</sup>

The content of any document, material or information provided by Cephalon to McKesson for inclusion in the program ("Supplier Content") under this agreement is the sole responsibility of Cephalon, and Cephalon represents and warrants that the Supplier Content complies with all applicable laws. Cephalon agrees to defend, indemnify and hold harmless McKesson for any claims, liability or expense whatsoever (including attorney fees) alleged to have arisen through violation of law by the Supplier Content, or infringement by the Supplier Content of any patent, copyright, trademark or other exclusive right of a third party, except and unless the claim, liability or expense arose due to McKesson's gross negligence or willful misconduct.



Exhibit B.135, David S. Egilman Report Opiate Litigation

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The signatory to this agreement has signature authority and is empowered on behalf of his or her respective party to execute this agreement.

\_\_\_\_\_  
Cephalon Representative                      Signature                          /    /      
Date

\_\_\_\_\_  
McKesson Representative                      Signature                          /    /      
Date

Invoice Address: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Email Address (if invoice can be sent electronically): \_\_\_\_\_

Product Manager:     Martha Torres-Morgan                      Date: January 19, 2012

NPO #: \_\_\_\_\_

Please fax this signed agreement to (415) 983-9144, Attention: May Chow  
or e-mail to [may.chow@mckesson.com](mailto:may.chow@mckesson.com)

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McKesson Manufacturer Marketing  
Cephalon, Inc.  
January 20, 2012

Page 6 of 6  
Proprietary and Confidential

**MCKESSON**  
Empowering Healthcare

HIGHLY CONFIDENTIAL-SUBJECT TO MDL 2804 PROTECTIVE ORDER

MCKMDL00353379

**OPINION- CARDINAL PROVIDED MARKETING TO MANUFACTURERS  
TO GET MESSAGES TO CVS.**

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Cardinal provided marketing to manufactures to get messages to CVS

**From:** Rachelle Galant  
**To:** Jinping McCormick  
**Sent:** 11/8/2010 10:01:52 PM  
**Subject:** RE: A multi-channel approach to maximize your sales

Interesting – I noticed they have Glenmark listed for Oxycodone 5mg long term backorder?  
Nothing on the 15mg or 30mg

**Rachelle Galant**  
Product Manager



Actavis  
60 Columbia Rd. Bldg B t +1 973-993-4527 @ RGalant@actavis.com  
Morristown, NJ 07960 United States w [www.actavis.com](http://www.actavis.com)  
Internal VoIP number t 125-4527

Please note that this e-mail and its attachments are intended for the named addressee only and may contain information that is confidential and privileged. If you have by coincidence or mistake or without specific authorization received this e-mail and its attachments we request that you notify us immediately that you have received them in error, uphold strict confidentiality and neither read, copy, nor otherwise make use of their content in any way. Please note that the sender of this e-mail and its attachments is solely responsible for its content if it does not concern the operations of Actavis Group or its subsidiaries.

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**From:** Jinping McCormick  
**Sent:** Monday, November 08, 2010 9:33 AM  
**To:** Rachelle Galant; Violet Wojtulewicz; David Myers; Karen Stoedter; Chris Gordon; Ara Aprahamian RPh  
**Subject:** Fw: A multi-channel approach to maximize your sales

Jinping

---

**From:** Cardinal Health Service Flash  
**To:** Jinping McCormick  
**Sent:** Mon Nov 08 09:01:52 2010  
**Subject:** A multi-channel approach to maximize your sales

Jinping McCormick, [welcome to this week's edition of the Service Flash!](#)  
[View the most recent Service Flash online](#) | [If you have received this in error, please unsubscribe](#)

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 Cardinal Health November 8, 2010

 Service Flash: A weekly product and service update to assist in your distribution needs.

Are you looking for a multi-channel approach to maximize your sales? If you can answer yes to any of the questions below, then **RxDeals** may just be the marketing program you are looking for:

- **Short dated product?**
- **Excess inventory?**
- **Seasonal items?**
- **Have a special promotional offer?**
- **Need a sales lift?**

Beneficial for both new and existing products, the RxDeals offering is customized to meet your unique needs and is designed to provide special offers – rebates or off-invoice discounts – to retail chain and independent pharmacies, including CVS and Walgreen's, to help move your product.

Contact your Marketing and Business Development Sales Representative today and RxDeal your way to maximizing your sales!

»[View this week's Service \*\*Flash\*\*](#)

Thanks and have a great week!

*The Marketing and Business Development Sales Team*

**Jeff Foreman, RPh**

Vice President, Strategic Purchasing / Branded Purchasing  
Office: 614.757.6674  
[jeff.foreman@cardinalhealth.com](mailto:jeff.foreman@cardinalhealth.com)

**Lauren E. Fields**

Director, Marketing and Business Development Group  
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[lauren.fields@cardinalhealth.com](mailto:lauren.fields@cardinalhealth.com)

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**Joseph Willaman**

Sr. Specialist, Marketing and Business Development  
Office: **614.757.2666**  
[joseph.willaman@cardinalhealth.com](mailto:joseph.willaman@cardinalhealth.com)

Questions? Contact [service.flash@cardinalhealth.com](mailto:service.flash@cardinalhealth.com)

Add [internet.team@ecomm.cardinalhealth.com](mailto:internet.team@ecomm.cardinalhealth.com) to your address book to ensure delivery. If you have received this in error, please [unsubscribe](#).

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7000 Cardinal Place | Dublin, OH 43017

## Exhibit B.299, David S. Egilman Report Opiate Litigation

## OPINION – WHOLESALER PERFORMANCE AGREEMENT BETWEEN PURDUE AND CARDINAL WAS A CONCERTED ACTION TO SELL AND PROMOTE OPIOIDS.

CAH\_MDL2804\_02890843 - Distributor Performance Agreement Key Terms - Seid

Dear Melissa,

As discussed with Aaron Lynch, Director Pharmaceutical Strategic Sourcing Branded Pharmaceuticals, on August 16, 2012, Purdue Pharma L.P. and Cardinal Health may undertake negotiations, in good faith, in connection with a possible Distributor Performance Agreement and other associated documents (collectively "Distributor Agreements"). Set forth below are the key proposed financial terms that may form the basis of any future Distributor Agreements between the parties (collectively "Term Sheet").


## Key Terms

DPA Fee at Risk	100%
DOH Range	32 – 40
Service Level	98% RAW (w/adjustments)
862/867 Reconciliation	5%
Term of Agreement	3 years
Termination of Agreement	60 days
DPA Fee	210 basis points
Inventory Appreciation Retained by Cardinal	36 days
Central Distribution	\$.45 per unit

The Parties agree that this Term Sheet is for a confirmation of agreed upon compensation to be included in the Distributor Agreements only, does not obligate any person to proceed with the proposed transaction and does not contain all matters upon which agreement must be reached in order for the

THE FOREGOING FORMS A BASIS TO CONTINUE NEGOTIATIONS, please so indicate by signing below and returning a copy of this Term Sheet to Steve Seid, Executive Director, National Accounts and Trade Relations.

Sincerely,



Russell J. Gasdia  
V.P., Sales & Marketing

Exhibit B.430, David S. Egilman Report Opiate Litigation

## **OPINION- MCKESSON HAD MARKETING AGREEMENTS WITH MALLINCKRODT, PURDUE AND TEVA.**

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MCKMDL00353368

MCKMDL00353261

MCKMDL00353277

## Exhibit B.430, David S. Egilman Report Opiate Litigation

**McKESSON**

**McKesson Manufacturer Marketing  
Product Promotional Agreement**

This Product Promotional Agreement ("Agreement"), effective as of September 8, 2016, is entered into between Purdue Pharma L.P. ("Supplier") and McKesson Specialty Health Pharmaceutical & Biotech Solutions, LP ("MSH"). In consideration of the representations, warranties and agreements set forth in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto agree as follows.

MSH agrees to perform the following services (the "Services") related to Supplier's product Butrans® Transdermal System ("Butrans") ("Supplier Product") during the applicable month(s) of the program:

**DirectRx Advertising:** MSH agrees to post Supplier's graphical ad with a link to Supplier's Supplier Product website (<https://www.butrans.com>), on McKesson's online ordering portal, McKesson Connect. The graphical ad will be posted for a total of four (4) weeks.

Timing: To be determined by Supplier and MSH but to be completed no later than December 31, 2016.

Service(s)	Fee
DirectRx Advertising (4 weeks)	\$21,000
Multi-Week Discount (15%)	(\$3,150)
<b>Total:</b>	<b>\$17,850</b>

MSH shall invoice Supplier for the amount of \$17,850.00 for the Service(s) and Supplier shall pay such amount upon receipt of invoice. The invoice will be available on the McKesson Supplier Portal ("Supplier Portal") within thirty (30) days after the launch of above Service(s). If Supplier does not have access to the Supplier Portal, contact [supplierportal@mckesson.com](mailto:supplierportal@mckesson.com).

Supplier will provide MSH with and approve all documents, materials and/or information, in any format, (including Supplier website links), for the Services hereunder ("Supplier Content"). It is expressly understood that MSH shall rely upon the Supplier Content to perform Services. Supplier represents and warrants that the Supplier Content (including any product or program described therein and any website content to which Supplier Content links), is accurate and complies with all applicable federal and state laws and regulations, including the federal Anti-Kickback Statute and the Food Drug and Cosmetic Act and its implementing regulations, policies and guidance. Supplier acknowledges that nothing herein requires MSH to perform Services relating to Supplier Content where MSH reasonably believes such



OPINION — WHOLESALERS WORKED IN CONCERT WITH MANUFACTURERS TO  
PROMOTE OPIOID USE THROUGH PHARMACIES.

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DDM00017023



## Request for Proposal (RFP) For Pharmaceutical Distribution

McKesson Formal Response  
June 9, 2011

- a. Please describe the Brand Rx purchasing programs available to Discount Drug Mart:

**McKesson Response**

McKesson's Prefer Rx<sup>SM</sup> program provides discounted pricing on the purchase of each item on the Prefer Rx Product List. McKesson also negotiates special contract pricing with manufacturers on over 150 branded Rx products and passes those savings to customers.

When a pharmacist purchases a branded drug that is on the Prefer Rx Product List, they automatically receive the Prefer Rx discount. The Prefer Rx portfolio is tightly managed, with additional pharmaceuticals being added to the program throughout the year. The opportunities are offered on a regular basis

Exhibit B.431, David S. Egilman Report Opiate Litigation

Basis: PPLPC004000239934

**MEMORANDUM**

**Purdue Pharma LP**  
One Stamford Forum  
Stamford, CT 06901  
Tel (203) 588-7315  
Fax (203) 588-6216

**To:** Steve Seid

**From:** Shelton Benson

**Re:** McKesson Ca.

**Date:** June 24, 2010

Met with Yuri Kasinsky and May Chow to discuss the current plans for the transition to reformulated Oxycontin®. The following are the key discussion points and results.

- The discussion I had with May Chow were to reconfirm our previous conversations and the meeting we had at HDMA. We talked about the two programs that seemed to make the most sense, Rx Bulletin and Fax Blast. The RxBulletin is going to require two weeks lead time. The Fax Blast can be done in 48 hours. As I was talking to May, working within their perimeters we may have some problems. We decided to meet at the trade show and further discuss the programs. We decided that the Fax Blast should probably go out one to two week prior to the 1<sup>st</sup> ship date and the Rx Bulletin go out on August 17<sup>th</sup> and 19<sup>th</sup>.
- Another program that just became available last week is the E-video Detailing program that is a 4 minute video that is on McKesson Connect for one week and on the Rx Detail Home page indefinitely. It is geared towards the pharmacists and gives them the ability to ask questions at the end of the video. The cost is \$7500. I thought this would be a great vehicle for RxPatrol. I presented the new RxPatrol piece to Yuri and May. It was very well received.

Exhibit B.431, David S. Egilman Report Opiate Litigation

# PPLPC004000244940

**To:** Seid, Stephen[Stephen.Seid@pharma.com]  
**Cc:** Siciliano, Cheryl[Cheryl.Siciliano@pharma.com]  
**From:** Benson, Shelton  
**Sent:** Tue 8/3/2010 7:36:39 AM  
**Subject:** FW: Oxycontin Reformulated Q & A Sheet  
MKCT-PHARMA-04189-07-10 OxyContinAd v1.gif

This give you an idea what we set up for McKesson Connect.

**Shelton Benson**  
**Exe. Nat'l Accts Mgr.**  
**Purdue Pharma LP**  
**Cell: 832-372-4336**

---

**From:** Chow, May [mailto:May.Chow@McKesson.com]  
**Sent:** Monday, August 02, 2010 9:05 PM  
**To:** Benson, Shelton  
**Subject:** RE: Oxycontin Reformulated Q & A Sheet

Shelton,

OxyContin ad is attached for your review. Once this is posted to McKesson Connect, customers can click on the "Order Now" button to take them to the ordering page where the reformulated items will be selected and customers can proceed to order if they wish. We will add a text link "Click here for more information" at the bottom of the ad which will allow customers to click and view either the FAQ or the 2-page retail sheet. Please confirm which one you want to link to the ad.


If approved, I have this scheduled to post August 16-22.

Let me know if you have any questions.

May

Exhibit B.431, David S. Egilman Report Opiate Litigation

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**From:** Benson, Shelton  
**Sent:** Wednesday, August 04, 2010 11:11 AM  
**To:** Seid, Stephen   
**Subject:** RE: McKesson Connect program

I'm not asking for your ok on the program cost. We have already discussed it. This is the program we decided to go with rather than the fax blast programs. It gets prime exposure for one week and then goes on the web site permanently. I was asking for your ok with the ad that they will be using that will drive the customer to the order page with the reformulated Oxycontin® and will include the FAQ sheet that we sent them. The cost is \$4500 compared to \$7000 for the other programs that did not get as much exposure.

**Shelton Benson**  
Exe. Nat'l Accts Mgr.  
Purdue Pharma LP  
Cell: 832-372-4336

Exhibit B.431, David S. Egilman Report Opiate Litigation

PPLPC004000245298

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**From:** Benson, Shelton  
**Sent:** Wednesday, August 04, 2010 9:10 PM  
**To:** Seid, Stephen  
**Subject:** Re: McKesson Connect program

Steve

Let me get back to you. That information is at home. I know the fax blast went out to 2600 but were limited to 2 pages which would not work with FPI.

PPLPC004000245474

---

**From:** Seid, Stephen  
**Sent:** Thur 8/5/2010 9:19:00 PM  
**Subject:** Re: McKesson Connect program

Go for it. Agree with you recommendations

---

**From:** Benson, Shelton  
**To:** Seid, Stephen  
**Sent:** Thu Aug 05 14:05:56 2010  
**Subject:** RE: McKesson Connect program

Steve,

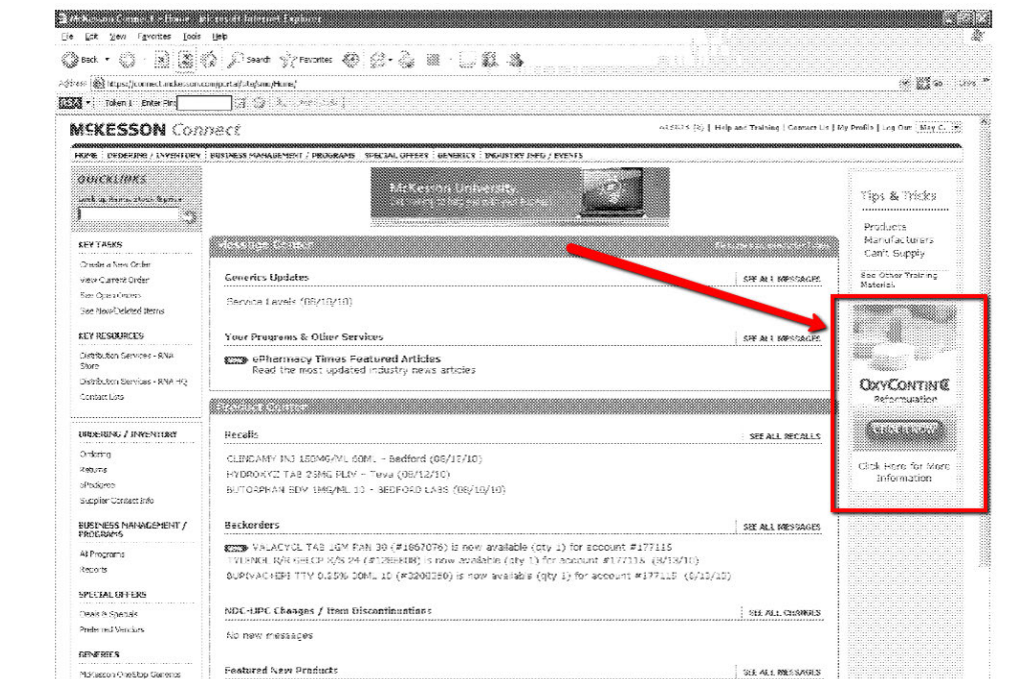
Just wanted to get back to you. With McKesson Connect the reformulated Oxycontin® will reach 38,000 customers 2 to 3 times, in all COT's. Just need to let May know if we want the information turned on the hospital COT. My recommendation is that we do. We get the primary spot for 1 week (Aug 16<sup>th</sup> thru 22<sup>nd</sup>), after that it will be on the McKesson Connect web site indefinitely. The cost is \$4500 compare to the original programs that we discussed, Fax Blast and RxBulletin, that would be a total of \$8500. We talked about we may want to do the RxBulletin, \$3500 in November as a follow up. That program is more of a HealthMart program.

**Shelton Benson**  
Exe. Nat'l Accts Mgr.  
Purdue Pharma LP  
Cell: 832-372-4336

MCKMDL00353308



## Exhibit B.431, David S. Egilman Report Opiate Litigation



## The Transition: Information from the Trade to the Trade

- Cardinal, distributed on line information to retail August 16 and August 23
  - Reach 33,000 stores per insertion
- McKesson, on McKesson Connect, reformulation information for a month
  - Reach 38,000 pharmacies
- ABC, on ABC Link
  - 9000 customers, 40,000+ hits per month
- Regional wholesalers provided information approximately 2500 independents
- Walgreens provided multiple internal communications to their staff starting in July
- Walmart began communication to pharmacy staff in June
- CVS provided staff information on the reformulation

**LEARN ADAPT ACHIEVE**

## Exhibit B.431, David S. Egilman Report Opiate Litigation



**PURDUE**  
Pharmaceuticals, Inc.  
Executive Director, Regulatory Affairs  
Purdue Pharmaceuticals, Inc.  
1000 N. Meridian Street  
Purdue Building  
Indianapolis, IN 46204-1329  
Tel: 317.342.1000  
Fax: 317.342.1001  
Email: [regaffairs@purduepharma.com](mailto:regaffairs@purduepharma.com)

**Stephen Seid**  
Executive Director, Regulatory Affairs  
Purdue Pharmaceuticals, Inc.  
1000 N. Meridian Street  
Purdue Building  
Indianapolis, IN 46204-1329  
Tel: 317.342.1000  
Fax: 317.342.1001  
Email: [regaffairs@purduepharma.com](mailto:regaffairs@purduepharma.com)

**Product Information and Inquiries**  
Purdue Medical Services  
1-800-729-7333

**Distribution Information and Inquiries**  
Purdue Customer Service  
1-800-477-1686

**FAQs Regarding the Information of OxyContin® Tablets**

**Q: Why the information OxyContin® Tablets is different?**  
A: This is a result of the requirement to change some of the physical properties of the original product to meet the requirements of the FDA. The information is being updated to reflect these changes.

**Q: Why the information OxyContin® Tablets is different?**  
A: This is a result of the requirement to change some of the physical properties of the original product to meet the requirements of the FDA. The information is being updated to reflect these changes.

**Q: Why the information OxyContin® Tablets is different?**  
A: This is a result of the requirement to change some of the physical properties of the original product to meet the requirements of the FDA. The information is being updated to reflect these changes.

**OXYCONTIN®**  
OXycodone HCl (CONTIN®) TABLETS

**Updated NDC Numbers for OxyContin® Tablets**

Strength/Quantity	Original NDC	Updated NDC	WAC
15 mg/100 Tablets	50011-055-01	50011-055-01	\$179.00
15 mg/100 Tablets	50011-055-01	50011-055-01	\$258.14
30 mg/100 Tablets	50011-055-01	50011-055-01	\$347.08
30 mg/100 Tablets	50011-055-01	50011-055-01	\$494.88
60 mg/100 Tablets	50011-055-01	50011-055-01	\$607.86
60 mg/100 Tablets	50011-055-01	50011-055-01	\$858.54
60 mg/100 Tablets	50011-055-01	50011-055-01	\$1,403.08

**ATTENTION**

**NDC Numbers for OxyContin® Tablets Targeted to Change August 16, 2010**

Please see NDC Information and Packaging Specifications.

**WARNING: IMPORTANCE OF PROPERLY IDENTIFYING AND VERIFYING THE PRODUCT**

OxyContin® contains oxycodone, which is an opioid agonist and a Schedule II controlled substance with an abuse liability similar to morphine. (2)

OxyContin® can be abused in a manner similar to other opioid agonists, such as morphine. This should be considered when prescribing OxyContin® to patients. Opioid abuse, dependence, and addiction are potential risks of OxyContin®. Opioid abuse, dependence, and addiction are potential risks of OxyContin®. Opioid abuse, dependence, and addiction are potential risks of OxyContin®.

**NDC Numbers for OxyContin® Tablets**

**Original NDCs for all strengths of OxyContin® Tablets are targeted to change August 16, 2010**

Strength/Quantity	Original NDC	Updated NDC	WAC
15 mg/100 Tablets	50011-055-01	50011-055-01	\$179.00
15 mg/100 Tablets	50011-055-01	50011-055-01	\$258.14
30 mg/100 Tablets	50011-055-01	50011-055-01	\$347.08
30 mg/100 Tablets	50011-055-01	50011-055-01	\$494.88
60 mg/100 Tablets	50011-055-01	50011-055-01	\$607.86
60 mg/100 Tablets	50011-055-01	50011-055-01	\$858.54
60 mg/100 Tablets	50011-055-01	50011-055-01	\$1,403.08

**Packaging Specifications for Updated OxyContin® NDCs**

Strength/Quantity	Dimensions (L x W x H)	Cube	Weight (lb.)
15 mg/100 Tablets	1.80" x 2.13" x 5.20"	0.01	0.10
15 mg/100 Tablets	1.80" x 2.13" x 5.20"	0.01	0.10
30 mg/100 Tablets	1.80" x 2.13" x 5.20"	0.01	0.10
30 mg/100 Tablets	1.80" x 2.13" x 5.20"	0.01	0.10
60 mg/100 Tablets	1.80" x 2.13" x 5.20"	0.01	0.10
60 mg/100 Tablets	1.80" x 2.13" x 5.20"	0.01	0.10
60 mg/100 Tablets	1.80" x 2.13" x 5.20"	0.01	0.10
60 mg/100 Tablets	1.80" x 2.13" x 5.20"	0.01	0.10

Type Company Name Here

**OXYCONTIN®**  
OXycodone HCl (CONTIN®) TABLETS

Purdue Pharmaceuticals, Inc. is the manufacturer of OxyContin® Tablets with NDC numbers. NDC numbers for all strengths of OxyContin® Tablets will change August 16, 2010.

Paper orders with the original NDC will not be accepted after [Type date here](#).

CCDC orders with the original NDC will not be accepted after [Type date here](#).

Strength/Quantity	Original NDC	Updated NDC	WAC
15 mg/100 Tablets	50011-055-01	50011-055-01	Type date here
15 mg/100 Tablets	50011-055-01	50011-055-01	Type date here
30 mg/100 Tablets	50011-055-01	50011-055-01	Type date here
30 mg/100 Tablets	50011-055-01	50011-055-01	Type date here
60 mg/100 Tablets	50011-055-01	50011-055-01	Type date here
60 mg/100 Tablets	50011-055-01	50011-055-01	Type date here
60 mg/100 Tablets	50011-055-01	50011-055-01	Type date here
60 mg/100 Tablets	50011-055-01	50011-055-01	Type date here

Please see accompanying Full Prescribing Information for Contraindications and all Warnings and Precautions, including Abuse, Misuse, and Dependence, and all other information.

Please send updated Order Billing and Invoicing.

**NDC/Packaging Update**

**OxyContin® 10 mg**  
(oxycodone HCl) controlled-release tablets  
(Targeted Date of Availability: August 16, 2010)

**Product:**

**Package:**

**NDC:** 50011-410-10

**Label:**

**NOTE:** This is a variable containing the date when the label is filed. Each label is printed on demand.

For information on this product please contact: [Purdue Medical Services Department at 1-800-729-7333](#).

PPLPC004000248656, PPLPC004000248973

Opinion - Cardinal delivered manufactures Marketing Messages to CVS





## Marketing and Business Development – Pharmaceutical

# Marketing Proposal

Prepared for

**Actavis**

Prepared by

**Kristine Fidler**

February 17, 2011



Actavis and Cardinal Health Marketing Initiatives

Per our recent meeting, please find within our recommendations for marketing initiatives to further create awareness and educate pharmacists on Fentanyl and Zolpidem. I have outlined those marketing programs that I feel would be most beneficial to your needs, including the Service Flash, eConnection, targeted Telemarketing and Direct Mail. As well, the Pharmacy Health Network is a great fit for Zolpidem to provide consumers with awareness of options they have for this class of drug. Pricing has been outlined and I have included heavy discounting where possible.

eConnection Program

The eConnection program will deliver your message to healthcare providers via email in an html format. In addition to your message, you can include links to your website and/or prescribing information (see sample attached in accompanying email). We can reach approximately **92,000 pharmacists** nationwide. Below is pricing for options, including discounted pricing for multiple sends. You can use different messages for each send i.e. for either or both Fentanyl and Zolpidem.

Reach and Cost:

eConnection to Pharmacists- One send	\$18,000 (Regular \$24,000)
eConnection to Pharmacists- Two sends	\$21,000
eConnection to Pharmacists- Three sends	\$31,500

Should you be interested in targeting physicians by specialty, I can provide a customized quote based on your specialties of interest as well, upon request.

Service Flash Program:

The Service Flash is a weekly publication distributed to all Cardinal Health customers (~32,000), including CVS and Walgreens. This piece includes weekly backorder and recall information, as well as ads from manufacturers promoting their products. Advertising opportunities in the Service Flash include a full page (8.5 x 5.5) or half page (8.5 x 5.5) ad space. A PI can not be included in the ad itself, however we can provide a live link for those customers who receive the piece electronically (approx. 1000 customers).

Below is pricing for Service Flash options, including discounted pricing for multiple ad placements. You can use different ads for each send i.e. for either or both Fentanyl and Zolpidem.

Service Flash Full Page Ad Costs:

Standard One Time Placement – Full Page Ad	\$9,000 (Regular \$12,000)
Two (2) Placements – Full Page Ad	\$12,000
Three or More Placement – Full Page Ad	\$5,000 per ad



**Service Flash Half Page Ad Costs:**

Standard One Time Placement – Half Page Ad	\$6,000 (Regular \$7,500)
Two (2) Placements – Half Page Ad	\$7,500
Three or More Placements – Half Page Ad	\$4,000 <i>per ad</i>

**Targeted Telemarketing:**

This program conducts targeted, customized telemarketing calls to our retail independents and Medicine Shoppe pharmacies. This presents an opportunity to survey the customer, to provide information and education on your product or to offer a deal to the pharmacy customer.

**Fentanyl**

We can conduct 1,166 calls to those Cardinal customers who have purchased at least one unit of the competitor product (Mylan Fentanyl) over the past 3 months.

Cost is \$7.25 per call (discounted from \$7.50 per call) for a total of \$8,453.50.

(Pricing subject to change based on message used.)

**Zolpidem**

We can conduct 275 calls to those Cardinal customers who have purchased at least one unit of the competitor product (Ambien CR) over the past 3 months.

Cost is \$7.25 per call (discounted from \$7.50 per call) for a total of \$1,993.75.

(Pricing subject to change based on message used.)

**Targeted Direct Mail:**

We are able to direct mail your piece(s) to Cardinal customers, and are able to co-brand the mailer with a Cardinal Health envelope. No other contents are included, the mailer is dedicated to your piece alone.

**Fentanyl**

We can mail to 755 Cardinal customers who have purchased at least one unit of the competitor product (Mylan Fentanyl) over the past 3 months. We can look to target this down further as a mailing this size could be cost ~\$5,000+. Please let me know if you would like to discuss further.

**Zolpidem**

We can mail to 5,502 Cardinal customers who have purchased at least one unit of the competitor product (Ambien CR) over the past 3 months. We can look to target this down further as a mailing this size could be costly (~\$20,000+). Please let me know if you would like to discuss further.



### **Pharmacy Health Network:**

Pharmacy Health Network (PHN) is an out-of-home digital signage network that provides you with access to millions of health-conscious consumers each month at over 800 retail pharmacies nationwide. Through flat-panel screens and brochure racks, PHN gets your brand directly in front of consumers at the point-of-influence. We target consumers with powerful and dynamic media, providing you with opportunities for targeted information delivery, and a measurable return on investment.

Opportunities include, but are not limited to:

- Ad placement i.e. static/flash ad spot to create awareness of product and disease state
- Brochure rack i.e. provide materials for consumers to take with them for further consult/consideration
- Sponsorship of 'news' segment

We can target 92 PHN stores who have purchased at least one unit of the competitor product (Mylan Fentanyl) over the past 3 months.

### **One or Two Month Campaign**

Element	Cost	Total Stores	One Month Total Cost	Two Month Total Cost (with 10% Discount on Ad)
Static Main Window	\$ 30.00	92	\$2,760.00	\$4,968.00
Brochure – One Brochure	\$ 36.00	92	\$3,312.00	\$6,624.00
Total Cost			\$6,072.00	\$11,592.00

Should you be interested in other combinations or additional months please let me know and I can quote accordingly.

Please do not hesitate to let me know if you have any questions. I look forward to working with you on your Marketing initiatives!

**Sincerely,**

**Kristine Fidler**

*Senior Consultant, Marketing and Business Development Group*

Cardinal Health

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